FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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RADIOLOGICAL HEALTH PROGRAM
STAKEHOLDER MEETING

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MONDAY,
OCTOBER 31, 2005

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The Meeting convened at 8:30 a.m. in the Montgomery Ballroom of the Hilton Hotel, 620 Perry Parkway, Gaithersburg, Maryland, Mr. John McCrohan and Mr. David Leslie presiding.

I-N-D-E-X

P-R-O-C-E-E-D-I-N-G-S

8:33 a.m.

DEPUTY DIRECTOR McCROHAN: Good morning. If everybody could take their seats, we will get our couple of days together started.

My name is John McCrohan and I'm the Deputy Director of the Office of Communication, Education and Radiation Programs at the Center for Devices and Radiological Health at FDA and I want to welcome you to this Radiological Health Stakeholders meeting.

I'm glad to see we have such a large and diverse group in attendance. I think that's a reflection of the diversity and actually the vitality of the Rad Health community. I think it's also emblematic of the diversity and complexity of the problems that we collectively face as we work to minimize unnecessary exposure to the American people.

A lot has changed over the years certainly since I began in the business 30 years ago and I think that it's important to understand all of the things that have changed. These changes have affected not

only our organizations individually and collectively but also the environment in which we operate. At CDRH, we've been thinking for some time about how we ought to respond to these changes and we've developed a radiological health program plan for CDRH which I'll be discussing in a little bit.

What became clear to us during our deliberations is that we can't afford to operate alone. We seriously believe we need to work together with all of you in order to effectively and efficiently address the Rad health problems that we all face. That's why we've convened this meeting so that we can all come together to share our views on important Rad health issues, to hear what we are all doing, to address the problems that we face and to learn what actions would be most effective in mitigating these problems.

I expect that we're going to have a very stimulating and interesting two days. As you'll see from the agenda, there's a lot of information to share today during a variety of presentations both this morning and this afternoon. We also plan to spend a

significant amount of time in small group discussion sessions tomorrow so that you'll have a chance to be involved in more specific conversations about the issues.

By the end of the meeting, I expect we'll have a broader and more common understanding of the problems that we face and a shared view of the priority of those problems and that's particularly critical for us. We'll have a common understanding I think of the important actions that are going on to address the problems that we face and a shared view of what yet needs to be done. Most importantly, we'll have identified opportunities to collaborate in taking actions to address those problems. I hope we all leave here with a renewed commitment to work together.

I certainly expect myself to learn a lot of things that I don't know and I suspect that may be true of a number of you and I hope you all help me in that by taking this opportunity to share your views on the issues.

I expect that we'll meet people that we don't know yet and I hope you're going to take this

opportunity to network with those folks on the breaks and during lunch because I think those contacts are going to be crucial in addressing the problems that we face related to unnecessary exposure. We certainly don't expect to finish the conversation at this meeting. In fact, we hope that this meeting will be the beginning rather than the end of a rich, on-going conversation and a source of continuing collaboration.

Now, I want to get us started by introducing David Leslie who is going to guide us through the process of the next couple of days and then I'll be back up here in a moment. David.

FACILITATOR LESLIE: Thank you, John. Good morning everybody. I'm David Leslie. As John said, my job is facilitator for the next couple days or resident border collie, however you like that. And what may turn out to be true is for you speakers when the blower comes on, we may wind up I'll just hand you my lavalier mike and you can talk from wherever you want if that comes on regularly. We'll work that as we go.

There are a couple of things as we get

started in this two days, if you'll allow, I'd like to kick off just because they'll just make the days a little easier. First, let me tell you what we were intending with this meeting and the agenda you have in front of you. This whole thing as we thought about it was to invite as many of you all as could and wanted to come to get in the same room to think out loud together about radiological health issues and looking forward. That was the fundamental underpinning of this.

The other piece was to allow for public comment which you'll see on the agenda. So if there are things that need to be said and things that need to be captured we get all that done.

Another piece of this is you will note you don't have in front of you copies of presentations and the like because part of our intention here is that all presentations and those things will be available electronically on the web within, I'm not sure exactly when, but soon. So we made a decision not to see if you could take down a whole forest and make a lot of presentations.

We've built in two distinct phases to this meeting. Today is a wide range of presentations which we hope will be educational for everybody in this room. You'll know some of the things you're going to hear. You'll understand and appreciate some of the points of view that you'll hear. But my guess is you'll find some other things where you'll go "Ah-ha. I didn't know that. I didn't know they thought about that in this way." So we're hoping just to enrich the discussion field with all the things you're going to hear today.

Tomorrow is a very different day. Tomorrow is having uploaded all of this today to give you an opportunity in some specific areas of the program that CDRH sees moving forward to get in a smaller settings and literally talk about what your views of the issues are, the things you think need to be made priority and how we can move this forward.

Our final part of the plan is for you to be able to leave here tomorrow afternoon having seen what comes out of those groups tomorrow. In other words, our plan really is for the facilitators and

discussion leaders tomorrow to be able to interact with groups all day long and before you leave here tomorrow afternoon say, "These are the themes that came out of each of these groups in these topics" so that you'll actually know what you and your colleagues thought at least at a high level about all this going forward. Then the rest will be available on the web.

Everybody got an agenda. Did you manage to get one coming in? Okay. A couple things. It is straightforward. Let me highlight a couple of things. We'll try to start at 8:30 a.m. right on the nose just because it's courteous to be prompt.

We'll be out of here this afternoon around 4:15 p.m., 4:30 p.m. I'm hoping that many of you would be interested in joining us out around the bar for rather much a no-host, meet and greet to say hello to each other and hang around and visit a little bit at the end of the day. If that works for you, fine. We'd love to have you. If it doesn't, so be it. But it's not something we have formally on the agenda. It's just we're trying to be opportunistic about that.

This afternoon we'll have the public

comment period from 3:15 p.m. to 4:15 p.m. Now let me say a word or two about that. In the announcement for the meeting in the planning that went on, I believe there was a request for those of you who wanted to make a public comment to either provide something in ahead of time or certainly your name and I think that has been done by some. When we get to that period, I'll certainly want those folks to queue up first and let that happen. But if there are others of you who would want to make some kind of comment, I will certainly make time to do that without any difficulty. We'll work that in terms of how many people there are who would like to talk against the time we have allotted for that because there is certainly the opportunity to submit things for inclusion later whether it gets said or not because that's an important part of this and we're perfectly fine with that. So we'll do that at the end of the day.

Tomorrow morning we will convene in here and then launch out into the session on the three particular topic areas. I'll talk about all that later and we'll work that.

Look at your agenda for 3:15 p.m. tomorrow afternoon. What I'm hoping to be able to do with that period is by tomorrow at 3:15 p.m. you will have heard a wide range of presentations all day today. You will have opportunity to participate in three separate groups all day tomorrow listening to your colleagues about these various topics. I'm hoping to come back in at 3:15 p.m. tomorrow and John and I will be up in front of the room and just hear what you think about all of this, your reaction to what you've heard, the things you think are smart, the things you think we should be doing, whatever your reactions are and whatever discussion points you would think appropriate to have considered by all of us, have an opportunity to have a very gently structured discussion about those kinds of things as we move forward, then get the themes from the breakout groups, wind up with closing remarks and we'll be on the road. So that's sort of the scheme. There's plenty of time in there for breaks. There's plenty of time for lunch. I'll talk about those in a minute.

One of the things to note is that we have

full transcription today and I think again tomorrow though we won't spend all of tomorrow of course in this room. Now the implication of that is this. When you have a question, we're going to ask if you would please to go to one of the microphones and when you speak at least initially on one of these if you'd be so kind as to say your name and your organizational affiliation so that our transcriber can get that early on. Some he has in front of him but not all. So that will be very helpful as we work the process and then all of that winds on the web.

Let me hit a few housekeeping items. Breaks and food. You've seen the break area out there. That stays pretty much the same and I think if we're lucky cookies appear in the afternoon, you know those no-sugar, low fat, not bad for you, those kind. But I think they show up later in the day. Eat them if you look.

For food, lunch, there's a couple of things to say. One is I'm told they do a very good buffet here in the hotel and I think that runs $14.95. There are, I haven't gotten my directions right here,

close by in the little shopping area there are lots of restaurants and I think we have a sheet out on one of the tables that list some restaurants if you have some preferences. I'm even told there's a Starbucks within striking distance.

Okay. Restrooms if you haven't found them already, there's two right here down the hall toward the main door and then there's another set on around the corner in the direction of the breakout rooms. This is the Montgomery Ballroom. It will be our main meeting room. We have three breakouts for tomorrow called the Gaithersburg, Frederick and Darnestown and they're literally, I'll go into it more tomorrow, down to the registration desk and then just straight down the hall. All three of those are just lined up. They won't be hard to find.

If you need any kind of assistance, if you need anything in the course of two days, please do one of two things. The desk that did registration this morning, go there. Ask those folks. They'll be happy to take care of you or see me. We'll make sure something happens to take care of whatever your needs

may be.

If people need to get messages, this is interesting. Ten years ago, the number I had to give out at the start of the meeting was always the hotel phone number. Now we all have cell phones and the hotel message traffic has dropped off a lot but I'll get to that in a second. If somebody needs to get a hold of you and wants to call through the hotel, the main hotel phone number is 301-977-8900. They could leave a message for you there and either our registration folks or the front desk, they'll handle that somehow or another and we can get that to you or you can check to get that.

By the way, if you don't know, the hotel is wired for wireless internet access without any kind of password. So if you have laptops, you can easily get on the internet without any difficulty here.

My one last request is would you please check your cell phones, put them on vibrate or off when we're in session and if you would if you need to make cell phone calls, please do those outside of the room so it won't be disruptive. This will happen

after lunch too. We'll all come back from lunch because we've done our thing during lunch. That's all right. We'll just work that.

That's the sum total of the administrative things that I had intended to say this morning. I guess the one last thing. Speakers, it would help us a lot if you'll work pretty close to the times we've have allotted to get through the presentations today because we have quite a few and I'm not sure what the window was. But if you can stick pretty close to the times that we set out, that would be helpful to get through the day.

Anything you want to ask about any questions administratively what I've not covered you need to know? Anything? Going once, twice. Okay. With that, John, let me turn it back to you and we're off and running.

DEPUTY DIRECTOR McCROHAN: This was the point in the program at which I was going to be introducing Dr. Lillian Gill, the Senior Associate Director of the Center for Devices on Radiological Health. However, I got a message this morning that

Dr. Gill came down sick over the weekend and won't be with us today.

So I'll say a few words about the topics she was going to discuss and then roll into my presentation. I'll be Dr. Gill for awhile and then I'll be back to being myself and I hope you will indulge me because I'm not doubt going to be repeating myself or herself as we go.

As we go back historically, it seemed fitting to talk a little bit about the waterfront if you will that the Center for Devices and Radiological Health covers. You can see a range of products and devices, the distinction being some of these things are electronic products that emit electronic product radiation, some of them while emitting electronic product radiation are also medical devices. We have authority under two different laws to regulate these products and their manufacturers. There is a therapy ultrasound system in the upper left, a cargo screening system there in the middle, a television, a cell phone such as David was talking about there a moment ago, laser light show projector, medical laser and a

radiation therapy treating planning system simulated here.

We have to cover a lot of ground. That could be attested to by former senior officials from the Center, like John Villforth over on my right who was the Director of the Bureau of Radiological Health and later for the Center of Devices and Radiological Health and was my boss's boss's boss, I think, when I started 30 years ago. We did our best to deal with all of the problems and issues and concerns about all of the products that were within our purview and I think at the time when it was the Bureau of Radiological Health back in the 70s we actually did a pretty sound job of covering this waterfront.

I think that the circumstances have changed. The world has changed. I mentioned that in my introductory remarks and a number of things have changed about the world that make it more difficult for us to cover this waterfront with the degree of thoroughness that we would have in the past and it leaves us in a situation where now we need to make much more serious choices about where we put our

energies, what kinds of products we address, what kind of problems we address with those products, what kind of approaches we take to addressing those problems with those products and so forth. And I think that that is certainly one of the driving forces behind our desire to have this meeting.

Amongst the various things that have changed over time since the beginning of the program are things with respect to what we call the product environment. Markets are now global. Companies are selling in this global environment and therefore are subject to all of the pressures associated with that.

And principal among those pressures are the requirement to meet standards that themselves are global or at least standards which exist in various countries around the world as well as our own. Back when we started, it's fair to say that the standards that were in place and important to manufacturers were the standards that we at CDRH had developed, the Mandatory FDA Performance Standards, that dealt with what went on in terms of manufacturing largely in this country. That has certainly changed.

At the same time, I think it's fair to say that manufacturing processes have advanced. There are a lot of things that have happened over the decades in terms of the development of quality systems and so forth which have led to better manufacturing processes. As I've said, we have these effective consensus standards in place, principally International Electrotechnical Commission standards, that deal with a lot of the products that we regulate and deal with those products as they're manufactured and sold in Europe and in other parts of the world as well. So the product environment has changed for lots of the products on that waterfront that we deal with from a regulatory standpoint.

In addition, we think public health needs have changed. The product problems that we saw in the past have largely been addressed. A couple of examples of those might be the concerns which led to the initiation of the program at FDA, concerns about the emission of radiation from television sets. That problem has largely been dealt with and we're not spending a lot of energy dealing with that today even

though we still have a mandatory performance standard for television sets.

This has translated into the consumer marketplace and I'm here to say this morning that I have done my part. I have bought my flat panel TV which as a matter of design cannot emit radiation. So I'm protecting my family and having a really big picture which is pretty cool. I think we're seeing that there are technological changes which have resulted in the problems of the past not being present today in addition to the work that we have done to address those problems particularly back when we were the Bureau of Radiological Health.

Another example might be microwave ovens. We have a mandatory Federal performance standard for microwave ovens and we have in the recent past not seen significant problems with that technology.

The shift of our concern has been to the medical arena which is certainly where I've spent almost my entire career. There were days in the distant past when a medical x-ray exam involved, as we used to say, a wall to wall x-ray beam where there

wasn't any collimation, where there wasn't any filtration and so on. We've long since passed those days and I think that the performance standards, the activities of the various organizations, professional and manufacturer and so forth and regulatory bodies such as outselves and the states have resulted in a situation where those problems with products, those fundamental problems of things emitting hazardous amounts of radiation or emitting radiation in places that they weren't supposed to have been taken care of.

Today, however, I think it's clear that the issues that we face are more related to product use and this takes us in CDRH and FDA out of our regulatory arena. We regulate the manufacturing of products and the performance of products, not their use with the exception of mammography where I've spent considerable amount of time over the last ten years. That's essentially our only foray into the practice of medicine if you will. But otherwise, we don't regulate product use.

But we see that the problems that represent public health risks today are essentially

problems that relate to product use. We'll go into that in some depth later on. So this is among the changes that have occurred and in addition to that, we have had changes at what was the Bureau of Radiological Health and is now the Center of Devices and Radiological Health which has led to an appropriate focus that is more on medical devices. Lots more medical devices, lots more possibilities for acute injury, lots more public health risk there. But that has led to a reduced emphasis and reduced staffing and so forth with radiological health responsibilities.

We had a fairly sizable program back at the time when I started 30 years ago. We now have about 50 staff working on radiological health issues and an additional 40 or so dealing specifically with MQSA and that's a substantial reduction from what used to be the case. So we've had changes over time in the product environment and what we perceive to be the public health needs and also our resources available to address those needs.

What hasn't changed clearly is the mission

that we have to protect the public from hazardous or unnecessary electronic product radiations and what hasn't changed is our commitment to that mission. What we've had to do is to refocus our efforts to address the public health problems that we face today.

Looking into the future, we have developed a plan with the intent of making ourselves adaptable to the changing standards environment, to focus some of our energies on monitoring the risks posed by radiation emitting products, be they devices or not, providing useful public health information and training to the industry, to users, to the public and to regulators ourselves and to the states, conduct research with practical applications practically applied and then manage our program internally in a way which maximizes its public health impact and that's the structure of the plan that we had put together.

What we're asking today, what Lillian would have asked today is that we stay connected, that we continue to collaborate whenever that's possible and that we remain committed to advancing the

radiation protection, the protection of the public and public health.

If you'll pardon me for a minute, I'll become myself again. We're almost on time. I'm amazed.

I introduced myself and my position a moment ago when I was making my opening remarks and alluded to the fact that I had been here for a long time. It has been about 30 years and just so that you know where I'm coming from for purposes of our conversations later today and tomorrow most of that time has been spent in the non-regulatory part of the agency's operation and most of that time has been spent dealing with ionizing radiation, in particular with the medical applications of ionizing radiation. But we do have staff here who have spent considerable periods of time dealing with the non-ionizing side, dealing with the non-medical applications of ionizing radiation. As I mentioned, a significant amount of my time over the last ten years or so had been spent, until a recent job change, with the implementation of the Mammography Quality Standards Act.

I mentioned the fact that I've spent most of my time on the non-regulatory side of the house because I think that's relevant to where we're headed, particularly since I have some responsibility for setting our course. And as I say, I think we will have more problems in the future to deal with that relate to use. Since we deal with these problems in a non-regulatory and rather educational fashion, I certainly bring that experience to bear.

It's certainly our perspective that the public health problems and issues that we deal with have changed over time but the mission certainly remains the same and the Center, through its process of planning over the last year or two, has refocused its radiological health program. We're looking to begin with you the ongoing conversation I mentioned and the collaboration or sets of collaborations to move forward collectively to address what we perceive to be the shared problems and, in fact, the priority problems where the priority is based on public health risk.

We have the goals that are related to our

plan of aligning our current efforts to the current and evolving public health needs allowing for more targeted regulation and we'll get into that in some depth momentarily, to expand our focus on the patient and the consumer because we see the use problems as the most significant public health problems and that's where both the impact of those problems fall and where some of the solutions to those problems may lie. And we see ourselves as increasing information dissemination and education. We'll talk about that in some depth momentarily and trying to, as best we can, improve coordination across the community an example of which is the meeting that we're hosting today.

This is our mission, to protect the public from hazard risks and unnecessary radiation exposures and we see needing to do that by maintaining awareness of the radiation emitting products and their manufacturers. We still retain that responsibility and that suite of products and manufacturers changes. Manufacturers certainly change if not from day to day at least from month to month and the products change themselves as new technology introduces new

applications of radiation for a variety of purposes.

We need to understand the emission of those products and the risks that they pose and provide public health guidance and direction as it relates to those products and their emissions. We need to certainly encourage manufacturers to comply with the appropriate standards. We are, after all, a regulatory body and we intend to pursue enforcement actions as necessary. We believe that there are opportunities to achieve our public health mission without needing to do a lot of the latter.

In terms of the program plan which you may have had an opportunity to see on our webpage, it's been up there since late spring or early summer, we divided the plan into these five areas and I'll talk about those in a little bit in some detail. But in terms of standards again, I think we see ourselves as needing to adapt to a changing standards environment and to work to acknowledge and work with the national and international voluntary consensus standards that have been developed.

In the monitoring area, as we've labeled

it, we're talking about paying attention to monitoring, overseeing radiation emitting products and their manufacturers and then taking appropriate regulatory action, if that's called for, based on the risk proposed by the products. So our degree of our monitoring, the intensity of our monitoring, have to be based on the public health risk posed by the particular products.

We also recognize that rather than simply monitoring products and their manufacturer, we also need to monitor product use. How are the various products that we're responsible for being used? By whom are they being used? In what circumstances are they being used? What are the radiation exposures attendant to that use? Where are the concerns with respect to that exposure? What can we do to address those concerns? Who are the actors? What are their behaviors? What do we need to do to affect that behavior? What leverage do we have? What incentives and disincentives exist in the system or what can we create to change the behavior of individuals to reduce unnecessary radiation exposure?

In terms of education, which is going to be a significant element of changing that behavior, we need to be looking at all of the stakeholders. We need to be providing more information and guidance to the industry so that it can comply with the requirements but also to users, to the public and to regulators like ourselves and the states. We need to be able to collaborate in providing training for all of those stakeholder groups. I think there are a lot of resources in this room that will help us accomplish that particular aspect of the mission.

In terms of research, we need to make sure that the research that we do within the Center is directed at specific radiation risks and has practical applications in practical settings and finally an internal piece, we need to manage the program internally as a single cohesive set of activities. In recent years, it has become somewhat fractionated. But there have been some changes which I'll talk briefly about that are going to lead to a more coherent program going down the road.

I want to talk briefly about each of the

components of the plan as we've outlined them and give you an idea of what our thinking is to date. We have goals with respect to the standards area of using performance standards that are on the one hand enforceable and on the other hand appropriate to today's technology.

As some of you may appreciate but certainly not as fully and deeply as Dr. Tom Shope who is responsible for this activity, it's difficult to amend an FDA mandatory performance standard. Our most recent effort came to fruition last spring I believe with the amendment of the x-ray performance standard which focused mainly on fluoroscopy systems and Tom was instrumental in getting that completed. But it took a tremendous, not to say Herculean, effort over quite a number of years to do that.

I think we need to find ways to be able to increase our reliance on these voluntary consensus standards, be they national or international, so that we can leverage the efforts that are being invested both by ourselves, who have a significant play in this area, but also by the manufacturers and others in

developing these consensus standards and bring that work and that effort to bear through our mandatory standards schema. That's going to mean establishing some process to assure conformance with mandatory standards and to encourage performance with consensus standards as appropriate.

It's our intention in this area to increase our participation in the development of international and national consensus standards focused on what we see as dose intensive equipment, those things which present the greatest risk to public health because they represent either the highest exposure or exposures to large segments of the population. We have, for some years now, been actively involved in the development of both national and international consensus standards and we continue to want to play that role and to actually increase our participation but in a focused way, putting our energy behind those standards which as I say relate to dose intensive equipment.

We also want to take steps to allow conformance to consensus standards by guidance and

follow that by adopting consensus standards by reference. An example of this, and the paradigm for this approach, is in the laser area where some years ago we issued a guidance which has come to be known as Laser Notice 50 which told laser manufacturers that it was okay with us if they certified conformance to the IEC laser standard in lieu of certifying conformance to the FDA mandatory standard.

We'd been involved in the development of the IEC laser standard. We were comfortable with the standard. To the extent that we had some discomfort, there are some exceptions in that guidance that says that it's fine to certify conformance with respect to these aspects of the standards but there are some exceptions where you need to conform to the FDA standards. It was an attempt on our part to, as I say, leverage the energy that was put into the development of the consensus standard and to harmonize our standards with those international standards to help the laser manufacturers deal with the more complicated world in which they were selling product across the globe and it would be convenient or

beneficial to them to be able to deal with a single standard.

So we took that step in the guidance to move in that direction and we indicated in that guidance that we intended to take the next step and adopt the IEC standard for lasers by reference. We are in fact in the process of working through that and we'll have something published along that line shortly I hope.

There is opportunity to do something similar in computed tomography, for example, where the FDA standard is currently couched in terms of a dose metric which was relevant to the single slice scanners of yesteryear but is less relevant, one would say, to the multi-slice spiral scanners of today. At the same time, we have an International Electrotechnical Commission standard which has a dose metric which is more appropriate for today's modern CT scanners. So we have an opportunity by guidance to say to manufacturers that it's fine with us if they certify in terms of the IEC dose metric rather than the older FDA dose metric.

That's one example. There are certainly other examples in ultrasound, potentially in other diagnostic x-ray areas and we're going to be working for and looking to opportunities to use these consensus standards appropriately within the context of the FDA's regulatory standards and regulatory requirements. Again, we're going to base that action, that activity, the priority that we give to the publication of these various guidances and so forth, on the risk posed by the product.

In the monitoring area, we certainly have the need to maintain awareness as I said of the radiation emitting products and their manufacturers, and to assess the electronic product emissions and the conditions of use. Again I would stress the conditions of use as something which hasn't gotten as much of attention in the past as perhaps it needs to now. We need as well to understand the effects of those emissions and the exposure risks. In terms of our intentions in this area, as we discussed in our plan, we're talking about requiring only essential manufacturing reporting. In the past, and even today,

Manufacturers are required to submit lots of reports to us which we don't have the staff to evaluate in the way that they were in the past and so we're going to, through guidance, provide exemptions to certain manufacturers from the various reporting requirements and again base these exemptions on the risk of the underlying product.

We're talking about moving from routine testing in the field or in the lab of units of product, to for-cause testing, when there is a particular problem identified, but more particularly to manufacturer inspections such that we can go look at the manufacturer's quality systems, what is it that's built into the design and manufacturing of that product that assures its quality and so on.

The manufacturing inspection component is not something that has been really significant in the past where we have really depended on testing substantial numbers of products in the field. In the x-ray area, for example, our history is to test about 1,500 x-ray systems a year at the point of installation. That represents maybe something

approaching ten percent, probably less than that, of the units installed and the basis of our oversight of the manufacturers and their associated assemblers has been these series of field tests. We feel now that we can get a better bang for our buck if we move to our manufacturers' inspections.

Part of this step is going to be getting away from routine radiation measurements in the field. In particular, eliminating the measurement of dose in the Mammography Quality Standards Act inspections is one example of stepping back from that direct primary measurement role that we've had in the past. Similarly, we will be phasing out the routine laboratory and field testing of diagnostic and cabinet x-ray systems, lasers, sun lamps, TVs, microwave oven products and so forth.

As a consequence of no longer having a program which involves the routine measurement of lots of units of product in the field, we're planning, over some period of time, to phase out our instrument calibration function in favor of simply maintaining instrumentation expertise and measurement capabilities

so that we can go and do the for-cause inspections and tests. Now we provide instrument calibration services to the FDA field which does, as I mentioned, in the x-ray area 700 or 800 field tests a year and we provide instrument calibration services to states who do an additional 700 or 800 field tests a year under what are called partnership agreements with us. Now, over some period of time which is yet to be determined, we feel it prudent to phase out that calibration service in favor of maintaining our expertise in instrumentation and our measurement capabilities. Again, this is all related to trying to put our resources where they will do the most good rather than to continue to do what we've tried to do historically.

Also in monitoring, going back to where we think the root of most of the problems are, it will be no surprise that we want to emphasize the assessment of use and the exposures associated with that use. Here again, we're talking about harvesting data that's gathered by others, by third parties if you will, rather than by doing direct measurements ourselves. Certainly this could involve adverse event reports,

reports of burns associated with fluoroscopy imaging for example, but it could also involve exposure and dose data associated with other kinds of medical applications, reports with respect to exposures from consumer products and so on.

One of the things that I think is clear is that we no longer have the capability to effectively sample and monitor what's going on in the country in terms of medical exposure. I would assert that, while we have over the past had a program called The Nationwide Evaluation of X-Ray Trends to monitor exposures in the medical imaging area, that program, which has gone on for some decades and has been very fruitful and has been the basis for similar but I think superior programs in Europe, isn't really adequate today to produce for us all a picture of what exposures are like in this country for patients involved in medical imaging procedures as those medical imaging procedures evolve very rapidly. So we don't have a way of getting a good, accurate, timely picture of what exposures are in this country. So to some extent, I think it's fair to say we're sort of

flying blind.

I think that there are efforts underway on the part of a number of organizations in this room to help address that particular issue. But it's certainly our view and it reflects back to what I said about the Mammography Quality Standards Act, we need to be look at ways which we can gather and compile and analyze and display information collected by others rather than feeling like we have to collect that information directly ourselves.

In the MQSA arena, as an example, and it's certainly an extreme example, dose has been measured in MQSA inspections for ten years. There have been conservatively 100,000 inspections done, a 100,000 inspections over ten years and we have found problems with dose in maybe one or two instances. Let me just go further and say that this is in a situation where at the same time the facilities that we regulate are required under the regulations to have a medical physicist measure the dose annually and the facilities are required to be recertified every three years and have their accrediting body measure the dose tri-

annually. So we have a belt-and-suspenders-and-I'm-not-sure-what system where we were measuring and measuring and measuring and there was really no problem to be dealt with. We have amply demonstrated that fact.

But I think it goes to the point that there are circumstances in which we, as the FDA, don't need to be directly measuring the exposure to the exposed population when there are others who can make that measurement and from whom we can gather collected information so that we have and you have a picture of what's going on across the country. That's a goal that we should be looking toward.

In terms of education, we certainly have a goal of a public that able to make informed choices about exposure in the medical, occupational, consumer settings, users who are able to minimize their own exposures and those of the people that they expose, manufacturers who are sensitive to radiation risk issues and able to respond effectively to their customers and regulators and state and federal radiation control programs that can effectively assist

users in minimizing exposure and risk. This is an area I think which needs considerable attention given the belief that we have that the problems that we face as a public health matter are largely problems of use.

It's our intention in this area to invest in the web as an educational tool and we're currently in the process of redesigning our radiological health portion of the CDRH webpage. But it's also going to call on us to create new web content to address priority issues be that guidance or a better display of data that we have or data that we may harvest from third parties as I was talking about a moment ago. We need to be able to keep that content current and up-to-date and focused on what we consider to be the priority problems so that it's available to those folks who are in a position to exercise leverage with respect to changing behavior to address those problems.

We also look to create a coordinated education program and to partner with a number of you, I hope, to disseminate information and create training opportunities. I think it's fair to say at least from

my point of view and from what I've heard, that it would certainly be preferable from the perspective of a manufacturer, let's say, to have an inspector visiting their facility who was relatively well informed and relatively smart about the topic. It certainly precludes, or makes less likely, the inspector doing something, I wouldn't want to say stupid, but let’s say inappropriate.

I think that similarly for facilities that are being visited by regulatory bodies it also is important for those regulators to be appropriately trained and educated and, I think, to the extent that we're looking at the medical realm, that includes being conversant with and having some understanding of or some acquaintance with the clinical applications for which the machines are being, used rather than simply focusing on the machine itself. I think we have a certainly have a challenge to meet going forward in that regard.

In terms of research, which is an internal activity of the center, we want to have a research program that is pointed at the high priority

radiological health activities, obviously conducted in accordance with the highest scientific standards as it certainly is and publicized in the scientific literature and in other appropriate media. But I think the key thing is to get that research focused on the high priority radiological health activities and that means getting our radiological health program people involved more directly in the selection of what research is done in the center and engaging the various managers at the various levels and assessing that value of that research as it goes forward in terms of the overall program.

Finally, we have a goal of delineating the management structure more clearly within the Center and getting it to operate more as a single program as opposed to a whole series of stove pipes which I think had become the problem as resources drained away leaving behind pockets of activities developed across the Center. We're establishing various teams and so forth to help direct the activities of the radiological health program within the Center. But it also involves implementing a communication strategy to

promote our program and to deal with our stakeholders as we are at this session over the next couple of days.

Having given you a rundown on the plan that we have, I think it's important to focus on some of the challenges that we face. I think for us it seems that there will be a challenge involved in staying aware of new technologies and new bioeffects information. Certainly there is a lot of evolution going on in the various technologies that emit radiation and it's going to be challenging to stay up on that to maintain some degree of not just awareness but some depth of understanding of the technologies as they evolve.

I think that in terms of the bioeffects information there are often things going on that are important in that area, the BEIR 7 Report being a recent example, where there can be impact on how we perceive the risks that we face as that bioeffects information evolves and develops.

It's also going to be challenging for us to make the decisions that we need to make, the

science based decisions that we need to make, in light of what may be the current public opinion about a particular issue. I think we need to go where the risk is. We've said that repeatedly.

But at the same time, the reality is that we need to deal with issues involving perceived risk. If we have a public that perceives that a risk is posed by a certain product we're going to be dragged in that direction. We're going to be required to deal with that particular. I think we have to try as hard as we can to give that issue the attention it deserves, that is to say to try to convince people that the risk associated with that product is whatever it is. Perhaps it's minimal. Perhaps it's nonexistent.

We need to be able to try to deal with that and not get too many of our resources committed where we don't think a significant risk exists. But we are inevitably, I think, going to have to commit some resources to those kinds of areas. We see it time and again where we get dragged in a particular direction by the perceptions of the public.

I think that goes to the next point of the challenge of communicating risks to a variety of audiences. I don't think we have as a community necessarily done as effective a job as we would like over the years in communicating risks. I think we have a public out there who has perceptions about risks associated with radiation which are not entirely congruent with what we may individually or collectively see as the reality of those risks. And as a consequence, people make decisions which don't seem to us to be reasonable.

I think that we need as a community to educate the consumers whether it's through the web or through other mechanisms about the risk or, as I said, the lack of risk posed by products and the radiation that those products produce. One product can have the potential to produce some immediate acute injury if it's used even in a typical situation but certainly if it's used in an atypical situation where there's more exposure than might usually be the case. Fluoroscopy is an example of that, laser certainly are an example, skin burns being the outcome.

On the other hand, another product may have the potential to produce a delayed injury either from a typical exposure or from an unusual exposure that may not appear for months or years. CT might be an example, as are other medical imaging techniques, and potentially, depending on the technology, security screening systems where the outcome might be cancer down the road.

Yet another product could be perceived to pose a significant risk when in fact from our best scientific judgment that risk is if any exists minimal.

It seems to us that the users of products, doctors in the case of medical imaging systems for example, need to both know what the risks are and be able to communicate those risks that result from the range of exposures to be expected from the products that they're using. There is certainly in the medical area, I think, a significant amount of data in the recent literature which suggests that that's not typically the case. People who use products that emit radiation are typically not really well versed in what

amount of radiation that particular product emits and what the consequences might be. And for other, I think the consumers need to be aware that there can be immediate risks, there can be delayed risks, and they have to be able to make a judgment about whether they should accept those risks or some alternative.

Screening technology is an interesting example. We go through airports now as many of you did coming here. There are various ways that you're being screened today. If we were in a foreign country, if you were overseas, there are other technologies that have been implemented using x-ray to screen personnel and you're faced with a choice. Do you want to go through the personnel security screening system or in this country, do you want to be sent downtown to the hospital and have a fluoroscopic examination or would you rather have the strip search? There are privacy issues which are going to have to be balanced against the exposure. That means you're going to have to know something about what the exposure issues are. You're put in positions where you have to make judgments where I think today people

have relatively limited information upon which to base those judgments.

It's going to be challenging for us to change the behavior of individuals in order to reduce exposures. We're all driven by different imperatives. Certainly I think, for example, in the medical area when you're doing medical imaging exam, the first priority is to get the clinical information that you need out of that exam to do whatever the task is with respect to that patient and deal with that patient's medical issues.

But I think that it also needs to be fairly high up on people's minds what the consequences of the exposures might be. People need to be thinking not just that the risk is minimal given the benefit I'm going to get from this particular exam but what the cumulative exposures are, not just to that individual, but to the population of individuals, whether we're creating more risks in the future, more cancers in the future, than we need to. We need to be mindful of what the exposures are that are being delivered and so forth and there are other examples.

We'll talk about a couple of those as we go forward.

In terms of changing people's behavior, I think we have to ask ourselves is it sufficient to give them more information. Is it dose display for a fluoroscopy system the answer or is it something else? Is the National Dose Registry an answer for the medical arena or is it something else? Is it combination of these things? It's certainly not clear to me at this point what the answer is.

In addition, we have a situation in which people are making decisions which we may think, from a public health standpoint, are inappropriate and it's outside of our control. We have asymptomatic individuals for example asking for a whole body CT screening exam. They certainly have perhaps a legitimate concern about figuring out whether they're well or not. They may not have enough understanding about either what the risks are or what the consequences may be when certain inconsequential findings appear on that CT that have to be followed up on because now I found something that isn't entirely normal.

We have expectant mothers who have an interest their developing fetus and when we have the issue of fetal keepsake videography. Again people putting themselves in a position to be exposed for a variety of reasons which we may or may not think are entirely appropriate. So how are we going to address and effectively change the behavior of those individuals when that's appropriate?

I think perhaps the biggest challenge that we have is prioritizing our efforts over what is after all a very broad range of products and issues that we might potentially have to deal with. Just as an example, here are some of the products that we have to come to grips with as a Center.

And to use a couple of examples, we routinely get reports dealing with mercury vapor lamps. These are light sources which are typically used in gymnasia in schools for example but they're also using in street lighting and security lighting and so forth. If one of these lamps gets broken and is not of the self-extinguishing type, then it can result in exposure to people who are close enough to

that lamp. For example, we got a report a few weeks ago of such an exposure in Tennessee where about 100 people in a gymnasium for a 9/11 event were exposed to the ultraviolet radiation from a broken mercury vapor lamp, about 18 of them requiring hospital treatment for the skin and eye burns irritation that resulted.

Here's a situation where we get two or three of these kinds of reports over a year. What level of effort do we put into that particular arena? There are as I said self-extinguishing lamps which in principle school systems and others ought to put into fixtures where they need lighting and where that lighting can be fairly proximate to human beings and where the human beings can be there for perhaps a significant period of time. Those lamps happen to be more expensive than the ones that don't self-extinguish. How much effort, energy, do we put into this? How do we encourage school systems and so forth to try to address this kind of a problem?

As I said, we get several of these every year and we're currently making a modest investment in an outreach campaign to educate the users of these

lamps and the hazards posed and encourage them to use the self-extinguishing lamps. That's being done through the web and through other mechanisms and this problem may be mitigated somewhat by existing newly revised building codes which get into this issue more directly.

In the security screening area, there are a variety of x-ray screening systems and technologies that are in use today, so-called cabinet x-ray systems such as you put your carry-on baggage through at the airport. FDA has a mandatory performance standard to insure that products are designed to prevent leakage from the systems. But these security systems are being put into more locations for more purposes and I think the potential for that downstream is greater.

The checked baggage that you may have brought you to the airport was put through a baggage screening system which may well have been hard to distinguish from a computed tomography system, a system which involves more radiation than a conventional baggage system. But again, NIOSH has been out to the airports doing studies for TSA, the

Transportation Security Administration, and is paying attention to the exposures to the workers in this regard and so far, there are no major problems I think it's fair to say.

But the screening technologies are likely to change over time. Their applications are likely to increase. Is this something we need to be paying attention to? Well, we have to the extent of being involved in the development of the national consensus standard under the American National Standards Institute for the personnel screening systems, those that are intended to screen human beings for security purposes using x-ray and we're currently involved in a similar standards development effort with respect to baggage systems and so forth.

We're also working with other Federal agencies to look at the questions that agencies ought to address if they're considering implementing or deploying some of these technologies so that we are asking the right questions and all asking the same questions using the same sort of approaches to get the answers about whether or not it's reasonable to make

the balance between the exposures that may be involved and the security benefits that may accrue.

I think it's true to say that the public who may be exposed in these circumstances ought to be educated more to the hazards as well as the security benefits and so I think that there are a variety of things that need to be done and we're working in this area largely in terms of developing in this case national consensus standards.

In terms of another non-ionizing source, there are problems that have come to light with respect to high powered green laser pointers over the past year. As we began to worry about those problems, we began to see reports in the literature of aircraft being illuminated by the green laser pointers and the potential problem here isn't limited to aircraft. There have been no reports of actual injuries or accidents but certainly those are possible and certainly if you were to be "lased" while driving your car there's certainly the potential for flash blindness or distraction that would be sufficient to cause an accident.

We have addressed this problem by educating consumers through the website through an article in the magazine *FDA Consumer*, through a web newsletter that's called *FDA and You* which is directed at secondary level schools and by conducting a variety of press interviews about the hazards of the green laser pointers. We've identified manufacturers of the illegal and noncompliant products, those that are too powerful to comply with the laser standard and we've taken regulatory action against them.

But it's interesting to note that while this has gotten considerable press so far as I know there were no actual reports of injury to date. So the question remains in terms of what priority ought this kind of problem to be given, what approach ought we to be taking to this particular kind of problem as we move forward.

Finally in the medical arena, CT procedures we would all agree contribute the greatest dose to the public of any medical x-ray procedure. There have been certainly articles to that point in the literature in recent years. In fact, a few years

ago, there was an article in the peer review literature which talked about concerns with respect to technique selection in pediatric CT which got picked up by that famous radiological health journal, *USA Today*, and made quite a little splash for a while. I think it's fair to say that it was a wake-up call to the medical imaging community.

I don't think anyone understood what was happening and what the consequences were of using adult techniques when examining pediatric patients on a CT unit. The fact is that those pediatric patients were, as I've heard, given doses that were perhaps three to five times what they might have needed in order to get the clinical information that was being desired.

Of course, when it involves children, it's easy to get people energized and I think the community certainly got energized. There was considerable discussion. There was guidance put out. There were educational activities and so forth to help mitigate the problem.

But I would ask whether or not we can be

sure that those activities were effective. What mechanism do we have to know today what exposure techniques are being used on pediatric patients or on adult patients for that matter? What do we know about what the typical exposures are for various kinds of CT exams for pediatrics and for adults? Again, I think we do the things which make sense in terms of trying to change behavior but I think it's fair to say that the behavior may still be going on and don't know if we don't have a good picture of what's happening exposure-wise in the United States. In addition to problems with inappropriate technique which was what is going on here, children being exposed using adult techniques and therefore getting more exposure than was necessary there are other problems.

I think it's fair to say the computed tomography may not always be used in a fully appropriate way. I think there are lots of pressures not simply from medical legal concerns but also from consumer themselves to have a CT exam of some particular kind in some situation, to have a CT exam for their child who has fallen down and hit their head

or has pain in their belly and there may be pressures to use CT in situations where the physicians and scientists looking at this practice would argue its not particularly appropriate way to to evaluate this situation.

It's clear that various groups have developed criteria for when a CT exam is indicated, but it's less clear at least to me how effective those criteria have been, how often they're followed, how well they're followed, again going back to the question of, do we know what's going on. How good a picture do we have of what exposures and technique and so forth are like in the medical arena in this country?

I would say that CT is just one facet of a broader problem and it applies rather obviously to CT but I think it applies to fluoroscopy and other medical imaging as well and I think the challenge that all of you in that area know about is that assuring that the right patient gets the right exam at the right time for the right reasons and the right technique and so forth and it's easy to say but how we

act to make that happen on a routine basis is a different question. I think that we need to look at the question of how do we address the users of CT systems and how do we affect their behavior in terms of these issues about technique as well as appropriateness of exams.

It won't pop up here because I didn't think about it while I was putting my slides together but if you notice hiding down in the lower right-hand corner from your perspective is medical accelerators. I point that out because historically CDRH has not done much in the way of activities within the radiation therapy sphere. I think, and again it's my ill-informed perspective, that that's because historically most radiation therapy was isotope based and because it wasn't a machine emitting the radiation, it wasn't our business. It was NRC's business or the agreement states' business. And I think it was certainly my perception that the medical physics was all over this, if you will. There was lots of support and attention being given to radiation therapy.

I mention this simply to ask the question that since more and more therapy is being done with machines today, is there any issue? Are we assured and, if so, how are we assured that the kinds of quality assurance procedures that are associated with isotope based therapy are actually being done with respect to machine based therapy using linear accelerates? From my perspective not having much background in that area, it's simply a question, but I think it fleshes out to some extent the range of issues that we have to deal with.

So I bring us back to the structure of the plan that we put together to make the point that while I think it's clear to us where we ought to be putting our energy that we ought to be putting some energy as I described in the area of standards, that we ought to be as a Center focusing on monitoring, that we ought to investing in education and so forth. It's less clear what the balance across those areas should be. It's less clear how those areas ought to be brought to bear, how work in standards or monitoring or education ought to be brought to bear on a particular problem

because I would think that the mix of effort would be different depending on the product, depending on the problem, depending on who we think has the leverage to affect whatever the situation is that's potentially leading to unnecessary exposure.

So it's one thing for us to say we want to do things in standards and monitoring and education for example. It's a different thing to say what the balance should be and how that balance should be changed or should be different perhaps as products change and as new technologies become available. I think that's what I'm certainly hoping that we'll get out of the discussions that we're going to have over the next two days.

So I would ask you that over the next two days that you participate, that you express your views, that you listen to all of the things that you're going to hear and there's going to be a lot of that, that you look for opportunities to collaborate with one another including with us and that you leave with a commitment to continue the work that we've begun here as I certainly think that there's a lot of

work left to be done. With that, I will stop and ask if there are any questions. We have ten minutes before break.

FACILITATOR LESLIE: If you have questions if you would please make your way to the mike and as you start please say who you are and your organization so our transcriber has it. Sir?

MR. BRITAIN: Bob Britain with NEMA. John, are they actually using x-rays to screen people in airports?

DEPUTY DIRECTOR McCROHAN: Not in this country. However, there are countries in this world where that is being done and there are circumstances overseas where that's being done. So I think it's fair to say that the potential exists. I'm not aware of any systems that are actually deployed, certainly not at airports in this country. I'm looking at Jill. I think there have been deployments of x-ray security screening systems in prisons and we've had conversations with folks in the Bureau of Prisons about that.

I think that with respect to the security

screening systems, particularly personnel security screening systems, we worked on the standards with ANSI and others who participated in that effort. So with the anticipation that this could be an issue, we wanted to get in front of it. But I think there are lots of circumstances that you can imagine in which someone would want to deploy some sort of security screening technology that might involve x-rays, so not necessarily today's problem but something that we've been looking at. Yes?

MR. McCORMICK: Yes sir. I'm Luke McCormick with U.S. Customs and Border Protection and we do have a few of those back-scattered x-ray machines deployed. They are a secondary system that we use. It's after we have somebody that we have targeted as a problem that might to be diverted to secondary. On the whole if I remember right, I think there were an average of two scans a month last year. So that's not a main issue.

But one of the issues that we are coming up to see is where the security screening systems are going to. Presently we're using three and four

megavolt linear accelerators. But some of the newer systems that have been proposed go all the way up to 15 MeV lin acc and we're starting to look at active neutron interrogation of cargo and 14 MeV neutrons and 14 MeV x-rays we're starting to look at problems of activation products or are there real issues in this? From our previous studies, we have not seen activation products at the pulse fast neutron analysis system that we've been testing but this is something that the public is very concerned about.

DEPUTY DIRECTOR McCROHAN: Is that largely for cargo purposes at this point?

MR. McCORMICK: Yes. That's strictly for cargo. In fact right now with the pulse neutron system, the dose to a stowaway should one actually get that far down the system is only about 8 millirem.

FACILITATOR LESLIE: Good. Thank you. Other questions? Please. One of the things we're hoping here is agreeing with everything John says is not necessarily a goal. But understanding what the thrust and intent of the program was clearly our intention with all this. Please.

MR. LEIDHOLT: Ed Leidholt, U.S. Department of Veterans Affairs. Question or perhaps it will be addressed later. Would you care to address what you intend for the NEXT program?

DEPUTY DIRECTOR McCROHAN: Let me just say something briefly. It's certainly my expectation that that program may well continue, but I think that, and this is my view, a program which on an annual basis looks at 300 or 400 facilities in this country and the exposures attendant to one exam is going to give us the kind of picture it's been giving us historically which is a very episodic picture. It's been very useful. It's been a program, I think, that's created a lot of the interest that exists in Europe and so forth. I simply ask the question whether or not it's providing us all of the information we ought to have about the range of exams particularly the different kinds of CT procedures for example that we might be interested in where the exposures are fairly high.

I think there's still a role. The advantage NEXT has I think is that it's a set of measurements made with a very tightly controlled

procedure with a phantom that drives the unit the way a patient would and so forth. So it's very good data. I think the problem is just, if you will, the sampling frame. So I think that there's a role for much more, if you want to look at this way, poorer data, less well controlled data, to give us some sense of what's going on in between both in time and in terms of imaging space if you will.

FACILITATOR LESLIE: Okay. A couple more?

MS. APPLEGATE: I actually have a comment if it's all right. I'm Kimberly Applegate. I represent the American Academy of Pediatrics and I'm a pediatric radiologist. I thank you very much for the comments particularly focused on CT and perhaps reprioritizing the issues to look at children's dose. I'll say though that if you look at this when you look at your list of challenges, one of the things that I think isn't mentioned that is very important is the driver of economics and medical reimbursement where CT is very profitable compared to some of the other things that we do that may be alternatives imaging in children.

DEPUTY DIRECTOR McCROHAN: Let me just respond by saying that I think that there really is some development in that area and it's certainly impression that the third party payers are getting more interested particularly in the higher costs medical imaging procedures and I think there are issues being brought to bear there in terms of quality and what kind of assurances facilities might be able to provide that they are doing a quality service and so forth for the third party payer's money. So we may be getting to a little bit of a nexus here that would be very helpful.

MR. BALTER: Steven Balter representing the Society for Interventional Radiology. I also happen to have a hat in the IEC and answering to several questions here, we have a project between IEC and NEMA called DICAM Dose where looking forward a year or two, all imaging systems that are capable of writing DICAM images in principle will be able to generate structured reports. You may have more data than you can deal with. Thank you.

DEPUTY DIRECTOR McCROHAN: That's better

than having not enough.

MR. BALTER: That's right.

MR. VILLFORTH: I'm John Villforth. I'm unemployed.

DEPUTY DIRECTOR McCROHAN: I think you worked long enough, John.

MR. VILLFORTH: I wanted to compliment you and the staff for putting this together. It was an excellent overview and it was very helpful to introduce it and get us thinking about the different areas.

I felt there was one area that was missing as far as CDRH was concerned and that is the non-machine, non-electronic product area. You do have at least one FTE devoted to what to do about emergency planning, Federal guidelines for emergency activities and so forth. Since this is a CDRH discussion today to look at all of the areas, I would hope somewhere that that gets put on the table because I think its' incredibly important as to whether the Department and whether the FDA and then more specifically whether CDRH is going to play a role in this or not. We're

hearing so much about what can happen with weapons of mass destruction particularly the radiological type and if something does happen, certainly FDA is going to have some concern or some involvement as it relates to the products that FDA regulates.

And then secondarily, the leadership question in the Federal Government. If I could back to a few years ago in 1979 when the Three Mile Island accident occurred, one of the things that impressed me tremendously was the leadership that then Secretary Joe Califano expressed to the Federal Government and that is that the issue around Three Mile Island is there was a real issue because it wasn't known at the time was a public health issue and that the public health, that is the Department, needs to take a bigger role as opposed to the role of the Department of Energy, the Nuclear Regulatory Commission, FEMA and everybody else.

My personal feeling is that it can't go away and I don't know where this might fit in to your agenda but it ought to be considered in terms of where CDRH goes in the future. Thank you.

DEPUTY DIRECTOR McCROHAN: I think an interesting historical anecdote, as you know, John, was the response of the Center to in terms of looking for what exposures might exist around Three Mile Island. Part of that response was to take some cards that had thermoluminescent dosimeters in them and nail them to every telephone pole we could find. What's ironic is that those cards were designed for evaluating mammography systems. So we adapt.

But I do think that your point is well taken in the sense that we really don't have a lot of resource in that area. It's one of the things that had Lillian been here she would have spoken to since she's the senior person in the Center responsible for coordinating counterterrorism and urgency response activities. But we do have one person working on this and we certainly hope that in the face of some potential if he doesn't get hit by a truck because we're pretty thin. But thank you for bringing that up.

FACILITATOR LESLIE: Are there other questions?

DEPUTY DIRECTOR McCROHAN: Maybe where's the coffee?

FACILITATOR LESLIE: Oh, they are letting you off easy. I'm surprised. Okay. A couple of quick administrative announcements before we head off to break. One is if messages come in for you to the hotel phone number and the like and wind up out at the front desk what I'm going to ask that the registration table do is just keep those out on the registration table. So if you're expecting anything, cycle by and see if there's one for you.

Should something come in however that's in the category of an emergency and we need to get to you quickly they'll wander around the room or even interrupt and we'll find out where you are because we don't have actual seating for who's sitting where. I would like to do that if I can.

The second thing is just a quick check. Do we have enough chairs? Those of you who are sitting, is that by choice or do we not have enough chairs for you? We're okay on that? Temperature in the room okay? Light okay? I know that's a dangerous

question always to ask. Ball park. Dying? How are you? It's a little too high. Not all the way to meat locker but a little colder.

DEPUTY DIRECTOR McCROHAN: I thought it was only too hot up here.

FACILITATOR LESLIE: I'll see if I can't make that. Okay. Let us then to break. We convene at 10:30 a.m. We will start the presentations. Bob, you're up first. We will get you queued up and ready to go.

(Whereupon, the foregoing matter went off the record at 10:05 a.m. and went back on the record at 10:32 a.m.)

FACILITATOR LESLIE: Okay. All right. Are you ready to go? So you said you wanted it cooled off a little bit. So we've done that. But as Charles up here a minute ago said to me having asked for a little bit cooler and gotten this he's not dare going to ask me for water. Wise man. In any event, now that we know that they bought the biggest and the best AC unit that could be bought on the planet, what I expect to do now is try to cool it off when we go

away for lunch or when we go away for breaks and what I have to calibrate is how long to leave it on. I think it will get us through until lunch, but we'll see.

Let's get into the presentations. We have a series of those for you and Bob Britain from the National Electrical Manufacturers Association is going to start that off. I think we've anticipated about 15 minutes each presentation. So, presenter, if you are through in less than 15 minutes, that's a little elbow room for questions. If you start running over that, I'll start dancing around and the like because what I'd like to do is get through the morning's presentations before we break for lunch and not have them jump over into the afternoon. Bob, are you ready? Bob Britain, you're on.

MR. BRITAIN: Ladies and gentlemen, if it is a privilege to be the lead off, I would have hoped that it would have been John Villforth. So maybe it isn't necessarily a privilege.

A little bit about me. John and I started this program. He preceded me by about a year and a

half with this. It was called the Center of Radiological Health then which later became the Bureau of Radiological Health under FDA. So I spent 23 years with the Bureau and FDA and leaving that going to NEMA and spending, I'm in my 20th year now at NEMA. All these years have been involved with radiological health. I'm privileged to say that. I'm passionate about radiological health technology, the industry and the government regulators.

What's a NEMA? It's a trade association and it's the largest trade association representing the U.S. electro industry. Electro industry means most anything electrical is covered, lights, lighting, electrical motors and even medical equipment. So we have a medical products department that covers anything from x-ray machines, CT, radiation therapy, nuclear medicine and medical imaging informatics.

NEMA historically has been known for its standards, known world wide for its electrical standards. We have electrical standards for just about every imaging modality and these standards work their way up to the IEC level where we're very happy

to turn them over to IEC committees who work to establish to an IEC standard. So between IEC 62B and 62C, all imaging modalities and linear accelerators are indeed covered.

The most recent and now quickly becoming the most famous standard we ever developed or had part in developing was the DICAM standard which is the Diagnostic Imaging Communication and Medicine standard. This standard is supported by 24 working groups unless we've gotten another one recently. And the standard is presently up to about 3,000 pages. This addresses all aspects of imaging, how to move images electronically over the wires, to archive them, to bring them back for viewing.

We try and stay close to our partners so to speak with the American College of Radiology and for example the American College of Cardiology, the Radiological Society of North America. We work very closely with the National Cancer Institute and soon we will be working much closer with the National Institute of Biomedical Imaging and Biomaterials.

What have we done historically with you

guys, with FDA, I should say? Way back in `67 and `68 we provided testimony for the Radiation Control for Health and Safety Act which was published in 1968. We've interacted with BRH on the x-ray standard going back to the early 1970s and with TEPRSSC and we've interacted with TEPRSSC, spelled with two s's instead in two c's, Technical Electronic Product Radiation Safety Standards Committee, that always has been a mouthful, on the sunlamp standard and the mercury vapor lamp standards where we provided some information and testimony to TEPRSSC.

NEMA had a major role in reclassifying MRI from Class 3 to Class 2 and that happened almost immediately after I went to NEMA in 1985. That was one of my goals. Then we've had a major role in developing ultrasound 510(K) guidance and even now we hope periodic meetings with CDRH staff and of course it's the topic of intense interest like CT dose and fluoro dose and other issues regarding fluoroscopes.

So just a brief mention, in NEMA's product scope there are products within your scope that are not in our medical program. But just to let you know

that NEMA does have some review and some activity with sun lamps and mercury vapor lamps and even arc welding machines which I think could fall under the Radiation Control for the Health and Safety Act because they do produce intense ultraviolet light and they are on circuit.

So these are the general comments. I hope I'm staying to the structure that was given to us by the CDRH folks. Here are the general comments. I want to just proceed all of this in that we don't have any magical fixes for you guys. So please don't expect any. Obviously we're in total support of the general direction you're heading, the concept of FDA RAD health program to focus the FDA resources where it's needed the most on the highest priority risks and where the questions are needed to be answered with the highest priority.

And we agree on the major program areas. The use of international standards, NEMA has supported IEC and ISO standards for years. So we have absolutely no problem in moving in that direction for CDRH.

Efficient monitoring, obviously. You probably are getting too much data in now that you don't know how to handle. So if we can make that more efficient, I think that's a good road to go.

Focused education, absolutely necessary. I'll talk a little bit about that later.

And research based on high priority questions, obviously we support all of these, all the directions you're taking.

So let's tease these out. On standards, I think we've all learned by now that FDA standards are just too expensive to develop and maintain and at least in the medical area and the imaging area, the technology is changing so rapidly and we've see this in CT. It's just too difficult to maintain the FDA X-Ray Standard to keep up these technologies. Referring IEC standards is very tempting to industry and I think it's probably very tempting to FDA also and especially tempting to us because like I said before, all imaging modalities are covered by IEC standards in 62B.

Now one note of caution in that I know you're going to adopt a reference or whatever these

standards and so FDA and industry should take a careful look at each of these standards that you're thinking about adopting because sometimes at the IEC they're developed with some sort of flexibility built into them and you have to be careful that they're not so flexible that both FDA and industry could find itself in an uncomfortable position when start to enforce these standards. So we need to look at each of the standards very carefully.

You have talked about a legislative change, some sort of legislation that would allow you to adopt. I think in your original document the word was adopt not so much reference but adopt. I think knowing the lawyers and the legal people, in FDA the Chief Counsel Office, I think they would be very careful about allowing anyone to adopt something without going through the routine administrative process of comment or publish proposal and comment and then publish final. So we need to take a look at that.

Monitoring. We need to make monitoring more efficient. We absolutely agree with you that

only requiring the most essential information is where you ought to go. We're going to suggest eliminating assembly reports which are called 2579 Reports for replacement components and not for new installations. Keep them for new installations but when each of those. Installations needs some replacement components perhaps where you have required 2579s every time you replace an x-ray tube, I don't think is necessary to have this paperwork coming forward.

We're going to suggest exempting x-ray equipment from any reports except CT and fluoro where I think you have the most interest and that's where the interest in the dose is. So we are suggesting that we keep those but eliminate the annual reports for the other x-ray equipment.

Now we certainly agree on shifting from the product testing to quality systems audits and inspections. I mean we've always come from that direction. We're on record of not supporting type testing. The testing you do isn't necessarily type testing but it's giving the hint to other countries that type testing is okay and we don't like that.

Type testing is expensive. It's happening in Korea and China and any hint of having the kind of type testing by a government especially FDA as okay to us is damaging. So we agree with you. Quality systems is the way to go. Most modern countries are going in that direction.

And I think that probably what you're getting at by giving up testing would be the microwave oven, door slams and the TVs which don't even have shunt regulator tubes anymore. But they still have screens, cathode ray tubes.

This is something that we have become quite interested in recently. There's a definite need for credible consumer/patient education and what we're seeing especially with medical imaging, diagnostic imaging, is that the public is being educated through the press. All we're seeing these days in the *New York Times*, *Wall Street Journal*, *Chicago Tribune*, the stories on imaging are coming forth and they're coming forth unbalanced. Most of them are negative and there's no balance. If the journalists were dealing with these issues with a sense of a balance, the good

with the bad or when they're talking about utilization/over-utilization, they could be talking about some of things that diagnostic imaging really saves, gets you out of the hospital two weeks earlier rather than surgery, whatever. Yes, we need education.

As a matter of fact, the coverage in the press was so, I have to be careful here. We felt the need to develop our own website so we could actually balance the picture of medical imaging. It's a great website. I think you would enjoy going into it. So please visit medicalimaging.org.

Research. Yes, we agree. Research based on highest priority questions obviously. That's the only way to go when your resources are so stretched and, yes, there should be an oversight committee. So that's short and sweet. We just plainly agree with you on your suggestions.

How can NEMA and CDRH work together? Well, we talked with some of our manufacturers and we think one of the contributions we can make is develop a list of relevant IEC standards that FDA could take a

look at and that we could actually certify to.

Education. We are willing to work with FDA to develop whatever papers or brochures you feel necessary to help you with your website. As a matter of fact, I've talked with our public relations program and suggested that we even develop a section our medicalimaging.org for consumer and patients and hopefully that would jive with yours. I understand you're wanting to develop one too.

The problem with websites is making them known and making them available and that's a bigger job. It's easier to do such a great job on a website but then people don't just show up and click on it. You have to make them.

And finally, we believe your plan is sound. It needs to be implemented. I think these two days you're going to get a whole lot of good ideas. We're ready to work with you. Thank you very much.

FACILITATOR LESLIE: Thank you. Give Bob a hand. Next up, American Association of Physicists in Medicine, Dr. Ritenour. One of the things I think you're going find from these today is you may very

well is occasionally the case, you'll see lots of agreement about that's a perfectly good direction to go. The question always gets down to so how do we do that and how do we do that together and that is what I hope we begin to stimulate the discussion around over these next two days. Sir, the floor is yours.

DR. RITENOUR: Thank you and thank you for the opportunity of commenting. I think many of you are quite familiar with the AAPM but I'm still going to go through the description of who we are and what we do. I'm Russell Ritenour, currently President Elect.

The mission of the AAPM is to advance the practice of physics in medicine and biology. We are into research and development, dissemination of technical information, educational and professional development, we spend quite a bit of time on that because our members are board certified and have to maintain their certification, and attempt to promote the IS quality medical physics services for patients. We are in charge of radiation safety during radiological procedures and many of our members

through their individual research have improved many types of imaging.

We also contribute to the development of therapeutic techniques such as prostate implants, stereotactic radiosurgery, multileaf collimators, tomotherapy and all of that sort of thing too. So medical physicists collaborate with radiation oncologists to design treatment and insure safety. The AAPM represents over 5,000 members.

So in terms of commenting on what the FDA is doing and planning and thinking about I think we're in pretty good agreement with the things that were mentioned in the RAD health plan overview just before the break and I think my comments will bear that out. We do agree that you need to concentrate of high risk areas such as interventional fluoro where there's a risk of skin injury, computed tomography where there is probably a significant contribution to population dose.

We're concerned about use of radiation and radiation producing machines by unqualified individuals. Radiologists have a great deal of

didactic training in radiation safety and that training is reinforced through the board exams that they take and we're concerned about individuals who don't do things to keep radiation doses as low as possible.

We believe that quality assurance programs should be designed by medical physicists and quality control programs too mainly because equipment changes and new modalities are introduced so rapidly. It's very difficult for anyone to be prescriptive about how to do these things. Medical physicists are there at the forefront sometimes inventing these changes but at least having to deal with them as soon as anyone does. So we think that we're in unique position to oversee quality assurance and quality control.

We also strongly support evidence-based regulation. One good example of this is the IEC program that was mentioned earlier that could gather a lot of data from DICAM headers. The AAPM and the ACR also have a joint program to look at the DICAM headers of computer tomography, computer radiography and CT to store and transmit to a central location information

on patient technique factors, indices of patient dose and that kind of data can certainly be the basis for what is the variation across the country and what are people actually doing which certainly plays a role in evidence-based regulation.

We do encourage the FDA to place more reliance upon the data that medical physicists take in mammography. That was mentioned this morning as well. Medical physicists have very strict requirements as to how to be approved to do mammography and how they have to survey a number of units under qualified individuals and do a number of units in a year to maintain that certification and that kind of data is probably a very effective way for the FDA to monitor what's going on in mammography, a very cost effective way and people effective way.

In terms of education, I think we can have a real impact in collaboration programs with the FDA. The AAPM currently provides hundreds of hours of educational programs at its annual meeting which occurs in the summer at various locations around the country and at the Radiological Society of North

America in the late fall. Some of that material, some of those classroom type presentations, didactic presentations would be of benefit.

But we also work specifically with groups such as CDRH and the Conference for Radiation Control Program directors to provide special educational programs at their meetings. Furthermore, the American Association of Physicists in Medicine has chapters throughout the country. So in terms of hand-ons training on equipment, there are some opportunities we could discuss there to work with academic programs or others willing to work with training people in specific locations given the difficulty of travel and the expense of travel to national programs.

Also we have several programs in place through our website. For example, there's the remotely directed continuing education which was put together basically to serve our members' needs to have continuing education credits and to maintain certification but it's certainly an appropriate way to glean information on current practices that would be useful to the CDRH and the FDA.

Also the AAPM has recently made its task group reports available electronically online to all radiation control program directors because we see that as in everyone's best interest to disseminate that information as quickly as possible on new findings and good summaries of best practices and quality assurance and quality control. So we look forward to working with the FDA quite a bit in areas of education because I think we're well set up to do that. I will end my comments there.

FACILITATOR LESLIE: Russ, Bob, both of you did a nice job helping us stay on track. If you have a minute, are there questions? Okay. You're both getting off easy. Okay. Next up, Consumer Electronics Association with Ms. Virginia Williams. There you are. Great. We have everything ready to go.

MS. WILLIAMS: Good morning everyone. Thank you to the FDA for inviting us. My name is Virginia Williams. I work in technology and standards for the Consumer Electronics Association or as many of you know as CEA.

This morning's presentation is very short and to the point. First, I want to tell you a little bit about CEA for anyone that doesn't know. You may think you know. It turns out we're probably more than you think you know already, the CE industry and how it relates to radiological health and then some interesting observations from our side of the industry and possibly how we can work together going forward.

CEA is a full service trade association. So for those of you that are in the association world, these are all very familiar activities. Our mission is to grow the consumer electronics industry. That means in a lot of cases innovation for new technologies and also to protect our industry from outside forces as well.

We do standards, government policy, research, education, the kinds of things that trade associations do. Our industry itself is very large and we are probably one of the broadest industries represented here today. We have over 2,000 members and every horizontal and vertical slice of the industry that you can imagine, everything from

manufacturers, our core base of members, the traditional members back to the days when the only consumer electronics there was was radio and these days everything is solid state, chip makers, service providers.

One thing I'll say at this juncture, our industry is so wide that it overlaps with a lot of other industries. So it's often difficult to classify products or technologies. One of the areas that is most overlapping in today's subject is microwave ovens and I want you to know that for the most part that sector of our industry is represented very heavily by AHAM. I don't know if AHAM is going to present today or not. But they have reviewed these slides and they concur with our recommendations.

In the area of technology and standards, my department inside CEA, we are broken down by a number of different committees that write standards or help other people write standards. R1 is the product safety committee and for the most part, they are not actively writing new standards.

Any of you that are familiar with the

standards' worlds have heard the expression, "The nice thing about standards is you have so many of them to choose from." Unfortunately, when you have so many you have none. So we're not in the business of just making work or trying to create new things just for the sake of new projects. Where there is an existing standard, it's our first choice to use that.

There are other aspects of the industry in terms of conformity assessment that are well established and we're very supportive of organizations like UL and other nationally-recognized test laboratories or OSHA calls them Nerdles. I think they're rethinking that term even as we speak.

There are a couple of areas of our website that give you more information about this and since we're time limited, I have some extra slides. If these presentations are made available, you'll see at the end more detail of each on the areas that our standards and our other departments work in.

I would like to just pause briefly and recognize some of the people that helped put this presentation together. As a trade association, we're

very member driven. Our R1 committee is chaired by JVC, Ted Marks, who is with us today and under R1, one of the many work groups that we have is radiological compliance and health and that's chaired by Wayne Myrick of Sharp who is also very instrumental in helping compile comments and as they say, herd cats.

These are some of the projects that we've done recently that relate. There are a number of others that probably don't relate to today's topic that I could go into. Our area of involvement in safety again is very wide. We've done things from stability of TVs based on their form factors to make sure that they're not a liability physically and mechanically to tip over and fall on people.

We've also done some work in audio health, the proper use of our products. One of the things that is very difficult in the CE world is constantly evolving technology. So as new things come out, there are new things that people didn't think of and part of how we help the public learn how to use these products is through the product literature that accompanies them. There are also product warnings and

marking right on the products and more general campaigns that we work with other partners to get the word out in educating the public on safety of our products.

This is another product area that we worked in, another initiative for manufacturers not so much for consumers but for the industry itself to help them know the proper ways to deal with radiation, x-rays and no TVs. It's meant for mostly offshore manufacturers, some guidance for them.

Most of the industry that we work with is very mature and very safe and they've been doing this for a long time. So it's not so much for 70 percent market share members that we worry about but the new guys, the smaller companies that are coming into the market.

In the area of product safety, I mentioned that we don't develop new standards where they are not needed. Our preference is to work in the international level with a number of agencies. We provide financial support. We provide support for experts to attend these meetings, to contribute and we

facilitate comments from industry funneled through these experts into these committees. We also lobby internally in the U.S. with other agencies and with government agencies for adoption of these standards where they're appropriate.

One of the things that we've noticed in the international front in the last few years is a hazards-based approach. It's a very systematic way of analyzing risk and understanding what the hazard is and how to mitigate against it, less prescriptive than in the old days. Part of a movement in a broader sense of object-oriented or performance-based standards setting.

By way of general comments, I think it's safe to say that our part of industry is probably not the highest risk area. That's not to say that we're not diligent but based on our track record, we think for the most part that we're very pleased to see the CDRH and the FDA in general look toward more progressive changes and automation and streamlining of the methods and focusing on the things that are more important, less on the things that are less important.

Having established a good track record, it's probably safe to say that the reporting that we're doing now is probably a bit of an overkill.

In general, our comments are going to be mostly about the reporting and monitoring process. In general in that area, we think that we can implement some reduced reporting in the annual report to minimize that and probably no need for a product report. The other area that we hear the most comments about is the custom's form itself and how much information is either contained on it or the guidance that goes with it and how to interpret some of the areas that need to be filled in.

In minimizing the annual report, the declaration of responsible party is probably sufficient and a master list of authorized manufacturers' names and their countries of origin or another method to identify the contact person, again keeping it simple and finding a responsible party in the U.S. which may or may not be the manufacturer.

We think that we could afford to do some relaxation of the reporting rules for Class 1

products. Lasers, televisions and microwaves are primarily the products that we're talking about and again microwave ovens is also represented by AHAM.

I think probably I'm not going to read this slide to you. On the customs form, echoing the same sort of sentiments about the responsible party, we think that this could be consolidated with just one box that has the manufacturer's responsible party of record. We could amend the instructions better to explain and interpret and allow import declaration without reference to the Class 1 products not specifically to the products but just to the party of record.

In generalized standards, we can probably help a little bit more with the how to. I know a lot of agencies are struggling with this at the moment, how to do two things, point to the standards in general, do you synchronize with them, do you point to them as a reference document, what if the standards contain options, how do you decide which of them you're going to allow, what about country differences. So there are a number of aspects that need to be

considered in harmonizing the standards.

The idea of relevancy and timeliness. As the standards evolve, how do the regs evolve with them?

Of course, recognition of compliance marking. In an ideal world, there's one mark that all countries recognize and the standards that the mark represents even if they're country standards, are harmonized one standard, one size fits all, to the extent possible and to the extent that the standards exist.

By way of example, it seems like there has been some attempt to do that but maybe not as smooth as it could be. An example is Laser Notice 50 which is only partially harmonized with the International Standards and this is ironically one of those areas where partially harmonizing is almost worse than no harmonizing at all. All that does is create an additional alternative and more complexity to the problem. So we would advocate full harmonization to the standard.

In the area of education, we have no

issues there to report but we are here to help and I have a feeling you're going to hear this from most of the stakeholders as well. We have as I said product literature that comes with the products, ways of marking the products, tags that go on the products, a long history of knowing how to get the consumer's attention appropriately.

And in addition to that, we have general awareness campaigns that we can help launch whether it's through a print campaign or other means, on the website. Many of you know that we put on the International CES every year and there's a lot of opportunity for coverage and for visibility to the retail channel. So a lot of training is done to the consumer through the retail channel.

Maybe a little more detail on these same thoughts will come out later in the workshop today and tomorrow. In general, we have a lot of opportunities and ways that we can be supportive in standards, in direct contribution of input for revisions that you're making in your program and in getting to the consumer, getting messages out to the consumer public.

One thing, it's always bad to end on sort of on a wagging-your-finger note, but I have to be honest. One of the comments that we heard was that we would prefer that you not cry wolf. If you want to make changes, then we need to make changes. There have been a number of attempts over the years that seem to have lost their momentum and probably more execution and commitment to the execution phase would be in order.

If we have time, I have more detailed slides but otherwise, I'll take questions.

FACILITATOR LESLIE: Questions?

MS. WILLIAMS: Thank you. That's no.

FACILITATOR LESLIE: There probably will be plenty of time for questions at breaks and lunches and the like. I suspect this will come later in the day. Thank you very much.

MS. WILLIAMS: Thank you.

FACILITATOR LESLIE: Okay. Next up, Ms. Christine Lung from the American Society for Radiological Technologists.

MS. LUNG: Good morning. ASRT is very

glad to be invited to participate in this FDA workshop because this is the first time we've ever been asked to participate. We are basically, I guess, the new kids on the block when it comes to regulations.

But in this overview, I want to frame this as more of an introduction to ASRT for you. I want to give you a little bit of the background, the role of radiologic technologists, some of the ways RTs and CDRH can interact together, some of the issues facing our workforce and radiologic technologists' needs as device endusers. As you all know, technologists follow the equipment and having the opportunity to comment when it comes to this aspect of imaging is very important to us.

ASRT is the largest allied health association in the world. Right now, we have a little over 120,000 members making up 48 percent of all registered RTs. This figure does not include the number of imaging technologists out there are either not registered or not licensed by states. We have no way of capturing that number but we know that there's a lot more people out there doing medical imaging than

what we really know to be true.

We represent diagnostic and therapeutic technologists performing in more 13 imaging and therapy modalities including radiation safety officers and quality inspectors and ASRT's role is to provide radiologic technologists with the knowledge, resources and the support they need to deliver quality patient care.

As I said, the clinical role of RTs is to provide direct patient care. With health care resources being stretched further and further, RTs are spending more and more time with the patients that they are either treating or imaging. We are using imaging equipment to emit ionizing and non-ionizing radiation for diagnostic imaging as well as therapeutic purposes. Our role in the clinical site is really to reduce and minimize radiation exposure to patients as well as to the workers, radiologic technologists and the public.

Radiologic technology as I said has not been directly involved with FDA or CDRH until MQSA came along. The technologist's standards put in place

by MQSA has helped us elevate the stature of our profession and be recognized more as a profession and more involved in patient care.

RTs are the equipment endusers. Our patients are the beneficiaries of that use. But when it comes down to actually putting the hands on the equipment, we're the folks and a lot of times we're not only just the enduser. We're the repair person, the designers of where it may go and we do a lot of input into how patient through-put goes on in departments.

We play a large role in educating patients. Since we have probably the largest amount of patient interaction in the imaging sites, we do a patient education work there and we also are branching into more of a research role in assessing the clinical efficacy of new imaging equipment and devices.

Since we are an old profession but relatively new when it comes to be out there in the public's forefront, we're finding out that there's a general lack of public awareness about the imaging

technology professions. Not many people know who RTs are. They assume that radiologic technologists are nurses or sometimes even physicians.

We really haven't been out there in the forefront and as a result of this lack of public awareness, we have also a lack of consistent and uniform professional standards. We still have states out there that have no education or certification requirements for persons who perform medical imaging, plant and deliver radiation therapy.

We also are seeing a difficulty with RT education not keeping pace with the emerging technologies. One facet of that that we're dealing with right now is fusion imaging, the combination of PET and CT for example. We have a number of technologists that are CT certified and a number of nuclear medicine technologists who are PET certified. However, when it comes to fusing those two distinct modalities together, you run into a personnel issue. They may be one but not the other.

We are currently coming out of a relative work force shortage. Three years ago, the American

Hospital Association reported that radiologic technology's vacancies in hospitals was eighteen and a half percent, higher than that of nursing.

We also are running into more and more workplace injuries because of lack of ergonomic design controls when it comes to equipment as well as patient lifting. So that is really an important issue to us right now. We're having a shortage in the work force and we certainly want to keep them healthy.

One way that ASRT can assist as endusers of devices is that we want to work with manufacturers in developing user education tools. As I mentioned, PET/CT has been a little bit of a speed bump for us. We really need to know what's going on in the manufacturing area so that by the time equipment hits the hospitals we have technologists that are educated and can fully utilize that equipment.

We want to assist in the ergonomic design of equipment including patient assistive devices. We realize that ergonomics is playing more and more of a role in the delivery of health care and with Americans tending to become a little bit wider as they are now,

getting patients into CTs, MRs and under C arms is becoming more and more of an issue. So we certainly want to make sure that we can get patients imaged and treated.

Also we want to provide input on methods and techniques to reduce radiation does to patient. This is really the most paramount we have on our list. Patients are relatively uneducated when it comes to the amount of radiation that they receive in medical imaging. We want to make sure that we can balance and provide some equilibrium for them when it comes to the medical necessity of the exam versus the radiation safety aspects.

Just a brief thank you. We really appreciate the opportunity to be here as well as we look forward to working with everyone when it comes to providing safe and effective patient care and we certainly appreciate the opportunity FDA and CDRH have given us to be here today.

FACILITATOR LESLIE: Okay. Dr. Charles Chambers representing the American College of Cardiology and the Society for Cardiovascular

Angiography and Intervention. You're on.

DR. CHAMBERS: Good morning and thank you for having me here this morning. As mentioned my name is Charlie Chambers. I'm from Penn State Hershey Medical Center. I've been Director of the Cath out there for ten years and Director of Nuclear Cardiology for about 15 years.

I'm here representing the American College of Cardiology and the Society for Cardiovascular Angiography and Interventions. The American College of Cardiology as most of you are aware is approximately 31,000 members, all aspects and basis of non-invasive imaging.

The Society for Cardiovascular Angiography and Intervention is a more specialized group of individuals where I serve as Board of Trustee for that group. I've been Chairman of the Laboratory Performance Standards Committee for about three years. That group is 3,400 and is involved in both invasive and interventional procedures.

You can tell an interventional cardiologist when he can't find a button to push.

Thank you. I'd like to again thank the group of CDRH and the FDA for having cardiology here today. I think what's important to emphasize is that cardiologists as a group, the American College of Cardiology, represents invasive, interventional, electrophysiologist, nuclear, but also cardiologist in training and as a group when we practice, we're actively representing the nurses and laboratory support personnel.

It's important to keep in mind and I think part of my role here today is to emphasize that we as a practicing cardiology group are routinely exposed to radiation ourselves and our patients and they rely on the cardiologist's judgment from the initial office visit into and including the procedure and more importantly, we are actively involved in these patients we see back in follow-up. We encourage the FDA and the CDRH to include all physician specialists that use ionizing radiation in their proposals and we're again thankful for the opportunity to speak here today.

My comments today will be initially a few

general comments and then specifically as requested to address monitoring, standards and education. First of all, as I'm sure most in the audience are aware, there's a significant variation between diagnostic and interventional procedures. Having performed over 10,000 diagnostic procedures and over 3,000 interventional procedures in my 20 year career, there certainly is a variation in those avenues and it's essential that those be separated with respect to standards.

The FDA from our standpoint, it's important when they put together standards to work to establish policy to talk with other organizations. OSHA is seeking to determine whether regulations in the workplace, ionizer regulations, should be modified. It's important that these regulations be coordinated with the FDA proposals.

We want to avoid any potential conflicting or burdensome regulations in the catheterization laboratory.

Though the NRC has not been involved in ionizing regulation, it's important that they be

involved if appropriate as well as any state or regulatory bodies.

With specific comments with respect to standards, the ACC and the SCAI are interested in the reference of the CDRH with respect to the challenges in enforcement of these regulations. We're very interested in how this program first into the FDA's June 2005 final rule on Performance Standards for Diagnostic X-Ray Equipment.

With respect to the comments on the CDRH plan on the global concept, several issues have to be addressed. In particular, the NCRP and ICRP, the coordination of the various groups need to be addressed and the FDA should be encouraged as it does today with incorporating the various organizations to be encouraged to engage manufacturers in these discussions.

I think the first presentation this morning addressed some of the CDRH programs and particularly the better classification of monitoring. What the ACC and the SCAI are concerned about with the respect to the CDRH monitoring section is to

specifically define what they mean by monitoring and I think John did a good approach with this earlier in the morning. But what we are concerned about is it's essential to include cardiology in this monitoring process.

There are various stakeholders in all areas of this incorporating data and particularly with cardiology with the ability to take these patients from before the procedure, follow them through the procedure and with follow-up we offer a unique perspective in the opportunity to see these patients long term. And with respect to monitoring if life long cumulative dose and things like that are involved, I think the cardiology group offers a unique opportunity for this.

Along those lines, the ACC and SCIA have several data collection vehicles, the SCIA with the Heart Rhythm Society and the Society for Interventional Radiology and NCC are working with the National Cancer Institute to field retrospective and prospective studies on operator radiation exposure in the catheterization laboratory.

A specific monitoring tool that the ACC offers to its 31,000 members and over 2,000 cardiocatheterization laboratories is the NCDR. The NCDR actually has three separate monitoring groups. It has the PCI where approximately 650 cath labs participate where they have over two million records of interventional procedures performed. It also has a database for implantable cardiodefibrillators and also is working on a carotid stenting registry that is now in place.

In 2003 with efforts from several people here in the audience, an SCAI nema-phantom was established for image quality assessment in the cardiocatheterization laboratory and we have that as an imaging quality assessment tool that's being put into place. But again, the ACC, NCDR and the imaging phantom registry are voluntary proposals.

We as a group were very interested in the educational component proposed by the CDRH, particularly the website issues. One of the earlier speakers talked about the limitations of websites, the importance of the ability of people to know what's

there and to access it. With the 31,000 members of the American College of Cardiology as well as the SCI database, there's a large number of access ability from our members to the various websites.

We have very active websites in both the ACC and SCAI. The ability to link these websites to a proposal with the CDRH I think offers a unique opportunity for both programs to implement particularly in the educational opportunities.

Over the years, the ACC has in conjunction with SCAI and other organizations has put together several documents in the area of radiation safety. Additionally with respect to the board examinations, we now have approximately 5,000 interventional cardiologists that are board certified in interventional cardiology. That board examination includes approximately 30 percent of the questions on imaging and radiation safety.

The documents that have been put forth by our society are listed here. In 1998, our first major publication from ACC. It was a general overview of radiation safety and an introduction of the IR

principle.

With respect to training in cardiology, we have our document published in 1999 and an overall standard for the cardiocatheterization labs. Again with some participants here in the audience, we are very pleased with the position statement that was published just last year, "A Clinical Competence Statement on Physician Knowledge to Optimize Patient Safety," which has been an excellent tool for the cardiology community.

And most recently in the area of CT imaging which we encourage all groups to be actively participating in, we published our clinical competence statement. That was endorsed by the Society of CT.

Again, I would like to thank the FDA and the CDRH for having us here today. It's my pleasure to represent the ACC and the 31,000 members as well as the Society of Cardiovascular Angiography and Interventional. We feel we offer a unique, broad-based, patient follow-up opportunity to work with this group and we encourage this to be achieved and we look forward to any opportunity to work with all. Thank

you for your time.

FACILITATOR LESLIE: Thank you, Charles. So first, thank you speakers for staying with the schedule. Now I don't know whether we twisted your arms and threatened bodily harm if you didn't stay on schedule or not but we've wound up a little ahead of schedule. So thank you very much.

I would actually like to take advantage of this being a little ahead of schedule and if you will allow a little period of open mike and if there are things that ought to get said, read into the record here, points of view, you are stakeholders in this radiological health business and there may be some of you that aren't scheduled to present that actually would like an opportunity to say something, to raise up an issue or something that we might not ought to overlook. So I would actually like to take a minute here and allow anybody that would like to speak an opportunity to do that. We'll still probably break a little early for lunch but it's an opportunity I'd rather not pass up.

Frankly, that includes the folks from

CDRH. If there are things that any of you would wish to say, I'd say you ought to feel free to step to the mike and have that say as well because this is a community of stakeholders and we all have a point of view in this and we all have a role to play.

So anybody's point of view on this is worthy of hearing. So let me say anybody that would like to speak either asking a question or make a statement please raise your hand or a head to the microphone. This was intended to be an interactive exercise. You're on. Just say your name again and say where you're from.

MR. McCORMICK: I'm Luke McCormick with U.S. Customs and Border Protection.

FACILITATOR LESLIE: Thank you.

MR. McCORMICK: And what I want to do is reemphasize what I've heard from a number of people here already. Make sure that any regulations you put out there are in conformity with the Nuclear Regulatory Commission, OSHA as well as all the other little regulatory agencies. Especially when you get into a nationwide program, it is amazing how many

conflicting regulations there are in the Federal Government alone. When we start adding in individual states, it's a mess.

FACILITATOR LESLIE: Wonderful. Thank you. Others? Tom, are you coming around?

MR. SHOPE: Yes, nobody else is.

FACILITATOR LESLIE: Okay. Cool. I was told you weren't a shy group. I'm a little surprised here.

MR. SHOPE: I wanted to make a comment and then maybe --

FACILITATOR LESLIE: Tom, identify yourself please.

MR. SHOPE: Okay. I'm Tom Shope with the Center for Devices and Radiological Health. One thing I wanted to just mention. There's top of regulation and I just want to make sure people understand, are aware and are thinking about the kinds of regulations, the kind of regulatory authority that FDA has and our authority to regulate comes through the Congressional legislation that gives us a charge or a mission or an authority to do regulations and those currently with

the exception of mammography which addresses the whole clinical practice of mammography gives us the authority to regulate the performance of electronic products that emit radiation and we can regulate the manufacturers and establish standards for which manufacturers have to conform and certify their products.

We also have the medical device amendments to the Food, Drug and Cosmetic Act that also gives us the authority to regulate the manufacturers by acting as gatekeepers to what can be marketed in the U.S. that's illegal to market products that haven't been either approved or cleared by FDA depending on the class of the product.

We don't have the authority to do anything else in terms of regulations. So I wanted to get that out there. We're not an authority to regulate the practice of medicine, how products are used. We could if Congress passed another legislation that gave us some of these authorities and equipped us to do those kinds of things. But we're not at that stage. So the thought that FDA is going to regulate occupational

exposures, what technologies can do, the kinds of monitoring that physicians might have to do of their patients, all those things are outside our realm of responsibility currently.

So that was my little comment to put in perspective what we can do from a regulatory standpoint. It can always if Congress changes something.

The second point I wanted to make was to ask a question and perhaps get people to think about, our current process for establishing mandatory performance standards which is the notice and comment rulemaking procedures as laid out in the administrative procedures. In Europe, they don't quite have that involved process to take an international standard and have it apply and be mandatory in the European countries. They have a method whereby they can through the CENLEC procedures which is basically a committee procedure.

If a international consensus standard is approved and thought to be effective for use, it doesn't have to go through notice and comment

rulemaking. So the point I wanted to pose is what is the opinion, reaction, thoughts of the group as to suppose Congress where to give the secretary the authority not to establish a mandatory performance standard by notice and comment rulemaking but the authority to recognize an international or national consensus standard developed by a consensus group in an open process recognize that standard and by that recognition require conformance with that standard for any product of that type sold in the U.S. It would not be the notice and comment rulemaking that gets into the environmental assessment, the regulatory assessment, the federalism assessment, all the assessments that are tied up currently in the notice and comment rulemaking, the whole cost benefit analysis stuff that is required when the Federal Government does a regulation. But if you're dealing with an international consensus standard that's been developed in a consensus process by the industry, interested professional groups, the regulatory groups of the various countries and voted on by the national committees of the countries, perhaps there is a

simpler process that we might use to adopt a regulatory approach to requiring conformance to international standards but that don't have the bottleneck that we currently have speaking from some firsthand experience recently.

We're not going to talk about this in any more greater detail today but I wanted to take the opportunity to pose that question to get people to think about how acceptable would that approach be. Would industry be willing to deal with that? Would the consumers think that's appropriate? Would they want to always have this notice and comment rulemaking process rather than relying on an international consensus standard? Food for thought hopefully.

FACILITATOR LESLIE: Good. So that's rhetorical but for tomorrow, Tom has either seeded the clouds or chummed the water depending on which image you have and the like. Okay. Other comments? Anybody else? This is a good time to get provocative if you want to put an idea on the table. The whole intention of the day. Wait sir. One and then you're next. Please. Before you start, then what we'll do

is if we finish you all saying anything early, we'll adjust lunch a little bit. Otherwise, we'll stay on schedule. Sir, who you are and where you're from first.

MR. MATHER: Rich Mather, Toshiba American Medical Systems. I just had a quick comment on Bob's thought about the website and the education for the general public. It's certainly disturbing and definitely a problem that the public gets all their radiological information from the press and via us. It think it's a great idea once we get it out there to make it available and seen.

My only concern and maybe a trick that we have to get to do it is that I think there's a general public mistrust of the government especially when it comes to radiological issues and whether they would believe it coming from a government body and how do we address that. I think there's a more trust of the press than there is of the government in general. So it would be good to get it out there but also to get it into a position that it's believable and they feel they can trust what they read. Just a comment.

FACILITATOR LESLIE: Cool. Thank you very much. Sir, you're next and then Bob, you.

MR. MORTON: I'm Bob Morton. I represent my own company, Quality and Regulatory Services and I consult for medical device manufacturers and have done so for the last 12 years. But I used to work at the Bureau of Radiological Health/Center for Devices and Radiological Health.

So I have a comment specifically at this time about these international standards. Bob Britain was right. It's tempting to just latch onto these but I served on a committee developing the international standards for IEC for radiation therapy equipment and it's not an easy process. It takes years. It doesn't keep up with technology and the application of that to get the CE mark is very variable. It depends on who you hire to get your CE mark as to what clauses of the standards they think applies to your device.

So it's not even uniform to get a CE mark for the same kind of device for two manufacturers if they use two different certifying bodies. The first thing is when they say I comply with IEC 601-1, the

Electro Safety Standard, it's impossible that they comply with all clauses. They don't make a device that has the need to comply with all clauses. So that's already wrong. They can't do it. But we say we do it. The manufacturers say they do it.

So to just shift over to an international standard is just pulling the wool over the consumers' eyes in my opinion because the consumer thinks the government is actually looking out for them and this perceived risk aspect, they think there's somebody protecting them from radiation and if you shift over to some international selectivity measure, they're not going to have that protection.

Lastly, what is the criteria for this risk base? Is it like the traffic light approach? Three deaths at an intersection and we can have a traffic light? How do you decide risk?

I'm also involved with companies in reporting adverse events to medical device reports, AROs and the like and I also know what's not reported. So I don't think you know what the risks are by looking at those and I also don't believe that the MDR

reports are analyzed today to look for risk because I know what the reports are that go in for some manufacturers and there should have been FDA action based on what was written. So I don't think you know the risk and I would hesitate a great deal to go to IEC standards for the new method of regulating this industry. Thank you.

FACILITATOR LESLIE: Good. Thank you. You know if these questions were easy, we wouldn't have to get us all together. But these points of view need to be heard. John.

MR. VILLFORTH: John Villforth. I'm going to need a little help on this from some of the old timers like Bob. But as I recall, the Radiation Control for Health and Safety Act's primary intention for regulating these products that were described here is through the Federal Mandatory Performance Standard of which you heard a lot about today and which I think it's been agreed has a lot of problems in getting those current and the enforcement activity that goes with it.

There is another provision of the Act and

that is the defect provision. Basically it says in the absence, I'm paraphrasing and that's why I need Bob's help, of a mandatory Federal performance standard if there was a product or a class of products in which there is problem, I don't know how to define that and these aren't the words of the Act, but there is something like that that is of concern, the FDA can come in and regulate that product as defective and require refunding of the money to the consumer, replacement or repair. I think those are the three Rs that were listed in the Act.

So on the one hand as we go about discussing this is that recommended approach of the Act of mandatory Federal performance standards. But there's something else in there which is not very clear and it probably depends to a large extent on the role of general counsel as to how much they're going to support something versus how much something is a minor discrepancy with some international or whatever kind of standard before you take action.

But there is a hammer in that Act that should not go unconsidered and that needs to perhaps

get on the table to get resolution to the people who are involved with the standard setting to get resolution on the part of FDA CDRH as to what extent might that be used and how extensive should it be. Is it left to the judgment of the people who see a defect as to what a defect is I think it is or what I call as a defect that's a defect or whether in fact there can be some clarification, just to put that other point for consideration?

FACILITATOR LESLIE: Good. Thank you, John.

MS. APPLEGATE: Kimberly Applegate again. From an enduser perspective, I would just like to raise a different issue which is that I understand regulations are quite complex for getting things on to the market. But as an enduser, I'm concerned about a lack of regulation of use of the equipment particularly the higher radiation emitters and in particular I think it would be interesting to address the oversight and this is just a check and a balance concept that we all understand given our government that there is no check and balance or very little

check and balance outside of the community hospital setting. If you look at where these devices are being used and where the growth is, it is not in the community hospital setting where there is committee oversight by professionals, but it's outside of that in specialty hospitals and in outpatient setting.

FACILITATOR LESLIE: Great. Thank you.

MR. MYRICK: Wayne Myrick from Sharp Electronics. I just have a general comment and a question. There's a group known as TEPRSSC that represents a lot of the stakeholders as spoken this morning. The question would be what role will they play in developing the plan and implementing the plan.

FACILITATOR LESLIE: Okay. Thank you. John, let me look to you. Is that a question that comes out of tomorrow or is that a question you actually have a view on you would want to talk to at the moment? It's really TEPRSSC's role going forward.

DEPUTY DIRECTOR McCROHAN: I don't know if that's going to be come out of tomorrow's discussions. One of the things that I would say is that it's clear if we take any actions to alter any of the mandatory

performance standards, any of our regulations, we have a legislative obligation to consult with TEPRSSC. So it's natural that they would be involved in some of the processes that we've been talking about vis á vis the standards this morning.

In recent years, we've tended to broaden their role and we've used them if you will as a sounding board and we've had conversations with TEPRSSC in areas that weren't really regulatory. How should we approach various things and so on? We haven't met with them really recently. There's not to my knowledge another meeting scheduled as yet but we certainly would expect to bring them up to speed on where we are and where we plan to head and use them in that consultative role even outside the area of regulations per se.

FACILITATOR LESLIE: Okay. Bob.

MR. BRITAIN: Bob Britain with NEMA. I just want to say a few things about the IEC standards or the ISO standards which are International Standards and I'm not going to completely disagree with Bob wherever you are, Bob. But I just don't think you can

throw them out. We just have to make them better, probably have to do a better job on the committee work if Bob is seeing that sometimes these don't work properly.

The world cannot exist without these international standards. A group like NEMA has to look globally. Most of our manufacturers are global manufacturers. We cannot have countries like China and Korea and Japan and Europe coming up with different standards. So where do you start? You have to start from IEC or International Standards and then they trickle down.

The other thing, Bob was talking about the CE mark and CENLAC and CEN these standards, yes they're taken from ISO and IEC and most of the time they're mirror images. Sometimes there are a few changes but they're voluntary standards. They're not regulatory standards.

In Europe, you are required, a device manufacturer is required, to meet essential requirements as part of their law. And you can do so by either saying that you will meet standards that are

directed to the certain essential requirements or you can describe how you can meet the essential requirements without actually meeting a CEN or CENLAC standard. I just wanted to clarify that for the record.

FACILITATOR LESLIE: Good. Thank you, Bob. Okay. I don't see anybody else standing up. Let's take this opportunity and go to lunch. Now as we do that, here's a couple of points. (1) We will have the room open and there will be somebody here. However, I would carry your phones with you. I do a little looking after your stuff. I don't know that it's not safe but I'm not prepared to guarantee that I'm going to sit on top of everybody's laptop for an hour and a half. So just know that.

Secondly, I would like to reconvene at 1:15 p.m. That's what your agenda says for the start time. When we get back, tell me whether the amount of time it takes to actually get fed is about right because then we'll know what to adjust if anything tomorrow for the lunch. Otherwise, we'll cool it off a little bit between now and 1:15 p.m. So we'll

reconvene at 1:15 p.m. Thank you very much for the morning.

(Whereupon, at 11:52 a.m., the above-entitled matter recessed to reconvene at 1:14 p.m. the same day.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

1:14 p.m.

FACILITATOR LESLIE: All right. Are we ready to go? Two quick things if I might as we begin this afternoon. First of all, does the amount of time we've allotted for lunch seem about right or did you

wind up with time on your hands you wished we would have been back in session? Is it about right? Too long? Too short? It's okay. All right. Good.

Second thing is check your cell phone please. Get them on vibrate or off or something. You know after lunch we all forget to do that, me included. Okay.

The afternoon looks like this. We have a series of presentations, then a break, public comment period. If we wind up with extra time, look for me to do open mike again and allow those who have something to provide us that prepares us to better discuss the issues tomorrow, we'd like to hear from that. We'll wrap up the afternoon with a few words about how I'd like tomorrow to go and then we're off. With a little luck, many of you will stay and have something with us at the bar and say hello to people you haven't yet met because this is a wonderful opportunity to put names and faces together and see old friends and make some new ones.

With that, let me get into the agenda. The American College of Radiology, Pam Wilcox. You're

on.

MS. WILCOX: Thank you. It's a pleasure to be here. Again as with the other speakers, I want to thank the FDA and CDRH for inviting us to participate. I think this is an exciting initiative and the ACR is very supportive of these proposed changes from CDRH.

I'm the head of the Department of Quality and Safety for the American College of Radiology and so I'm going to primarily focus on what we do within that area of the organization. But just to give you a little bit of background about who we are for those of you who don't know, there are over 30,000 members in the ACR. It includes radiologists, radiation oncologists, medical physicists, nuclear medicine physicians and interventional radiologists. There is more than one interventional radiologists.

This is the mission statement of the ACR. I think it's key to thinking about what we're doing and how we can collaborate as a community of radiology and with the FDA and CDRH. Our primary focus is advancing the science of radiology, improving the

quality of patient care, providing continuing education for radiology and allied health professions and conducting research for the future of radiology. All of these go very nicely with the proposals that we've been hearing about all day.

First of all, we have practice guidelines and technical standards. These are very different than what we were talking about in the context of standards this morning. They're really more looking at specific training skills and techniques. They don't focus as much on dose. Although we do have a practice guideline that's in physics for the reference values and we'll talk a little bit more about that later.

There are educational tools designed to assist practitioners in providing appropriate radiological care for patients. There are over 160 of them now and we go through a consensus building process and then they are approved by our council at the annual meeting. However, they are not intended to establish a legal standard of care but rather to be educational pieces.

We have accreditation programs in all of these modalities. As was mentioned earlier under the Mammography Quality Standards Act, the ACR is the national accrediting body. There are a number of states that also accredit within their borders. We accredit 12,975 units in the country currently. So these numbers are unit numbers.

We also have programs in stereotactic breast biopsy and breast ultrasound and biopsy. CT is a relatively new program and we'll talk a little bit more about some exciting data that's going to be coming out of that program now that it's reached its three year anniversary. MRI. Nuclear medicine. The PET program again is also relatively new but may fit well with some of the things we want to do here.

We have appropriateness criteria. I was pleased to hear John say right exam for the right reason, done the right way, with the right dose. Right now, appropriateness criteria is doing the right exam for the right reason. Given a set of clinical conditions, what is the right exam, the most appropriate exam to be done for that patient? It's to

enable referring providers as well as payers to make the appropriate decision about imaging. We are in the process of looking at dose and linking dose to the appropriateness criteria, too. So there will be even a stronger educational tool going forward.

Other products that are in the Department of Quality and Safety include quality control manuals in mammographies, stereotactic breast biopsy, MRI and the ever popular barium enema. They're already asleep.

We also have a program called RADPEER which is a peer review program for radiologists. As they're doing interpretation, they pull out old cases from the jacket and they score according to whether they agree with the diagnosis that was made or whether it was a miss. And it's a quality improvement program. We collect data. It's all deidentified but we provide benchmark reports back to the facilities.

BIRADS, anyone in mammography or breast cancer is probably familiar with this lexicon that was originally developed in the very early 90s by the ACR and now includes not just mammography but MRI and

breast ultrasound.

We also have a white paper on MRI safety. One of the things I'd like to hear a little bit about is is there any role for the CDRH in MRI. No, it's not radiation but is there something that we should be looking forward to given the safety issues in MRI?

I want to talk a little bit about our new initiatives because I think these are some things that will be very much interesting to this group in going forward in collaboration with the CDRH is very viable and would be very exciting. I mentioned earlier that from CT accreditation we have dose data. We have data from over 820 units collected through the accreditation process over the last three years and the dose data is compared against the reference values, so the adult head at 60, adult abdomen at 35 and pediatric abdomen at 25. We had a meeting just last week to look at this data. We're going to be doing some further analysis and expect to get a paper out early next year to really get the word out about how to reduce dose and optimize image quality. That's what this is really all about. We'd like to work with

CDRH on disseminating this information going forward.

We have another new initiative that we'll be kicking off right after the first of the year. It's a dose reduction program and again, we'll be inviting CDRH to appoint someone to participate in this committee. It will be an effort to educate radiologists and radiologic technologists about ways to achieve diagnostic quality images with the lowest dose possible. We are all familiar ALARA but ALARA often, I think, motivates people to do optimal image quality when acceptable diagnostic quality doesn't necessarily mean the same thing and we may be able to reduce significantly more.

We need to educate referring physicians and Dr. Applegate talked about the issues with pediatrics. We really need to get the word out to the referring physicians about dose issues and to the public as John was speaking about this morning, choosing the right exam for the right reason with the lose possible radiation exposure. Again, as I mentioned earlier, we're going to be linking dose to the appropriateness criteria as part of this

initiative. We really need to get the message out what diagnostic quality is versus optimal image quality.

Another new initiative is what we're calling National Radiology Data Registry or NRDR. And NRDR will be an umbrella registry that will include modality registries, for instance a PET registry and that's been mandated by Medicare. There will be a registry for carotid stenting as well.

Then under GRID which stands for General Radiology Information Database, we will be looking at performance outcomes as well as adverse events, contrast reactions, things like that. RADPEER that I mentioned will also fit under this registry and then the Dose Registry that Dr. Ritenour talked about this morning in terms of collecting dose from CT will also be a part of this data collection. So as time goes on, we'll have a really rich database that will allow us to mine it for real benchmarks and educational materials back to facilities as well as on a more universal basis through publication.

So having said all that, I think there are

lots of opportunities for collaboration. Sharing data as part of the monitoring initiative of the CDRH can be done through projects like the CT Dose Collection Initiative. Coordinating dissemination of new data and guidance, educational programs through the CDRH, again I think there is a lot of information that radiology and oncology radiology has to share but we need to find multiple avenues to get the information out there.

Clearly, we can reach the radiologists and the medical physicists in our community. But how do we reach the other physicians who are using imaging? How do we reach patients and payers? I think looking to CDRH to help coordinate that as well as facilitating international cooperation. We heard about consensus standards this morning. That's going to be a key element going forward.

I was pleased to hear John talk about the use of consensus standards rather than mandatory standards. Because as we all know, the way technology is evolving so rapidly if we have mandatory standards the unintended consequences could certainly be to

limit technology going forward. So with that, I will finish.

FACILITATOR LESLIE: Any questions? John.

DEPUTY DIRECTOR McCROHAN: I'm John McCrohan. One of your slides, Pam, talked about the CT dose collection and the reference values and I'm struck by the fact that at least at the moment there are in CT reference values for the adult head, the adult abdomen and pediatric abdomen. I guess my question is for you and for others and perhaps for conversation tomorrow is that a picture of what's going on in CT. Does that have sufficient granularity? Are there enough reference values for the purposes that we have collectively in mind? Is it sufficient a sense, let's say, of what the national average is for CT or whatever of the head, the chest, the abdomen irrespective of the procedure that's being done in that area?

You mentioned a number of things where if you're going to do a stent placement, you might do a procedure one way. If you were going to do a general diagnostic survey, you might do something else. So in

theory, how far ought we to go in terms of trying to make our picture of what exposures and doses are richer using CT as an example of those three things where we ought to be or are we hoping to go further with that?

FACILITATOR LESLIE: John, I think in terms of the dose registry beginning with CT it's going to be key. The concept as I understand it, and I'll ask Dr. Ritenour to speak or maybe even Jeff may be able to speak to this more since this is an AAPM ACR project, it's my understanding that the idea is you take an exam and you will be able to through software automatically upload to this registry what your dose is for a given exam. I think that's the kind of data that we're really going to need.

Head and abdomen are important. The reference values come from Europe. But as we were talking about last week at our meeting, you're doing a liver and how many times do you go through the same body part to do an abdomen? So what's the real effect of dose as opposed to these particular reference values? I think we can get there.

How we will achieve participation in the dose registry is another issue. That's one that worries me a little bit. In an environment where most imagers including the technologists as well as the physicians are overtaxed, time is of the essence. How do we make sure that we get out what we really want to get out without adding to the burden?

FACILITATOR LESLIE: Good. Thank you, Pam. Next, Dr. Geoffrey Ibbot, American Society for Therapeutic Radiology Oncology. We have you ready to go. Great. You're on.

DR. IBBOT: Great. Thank you. Yes, I'm Geoff Ibbot. I'm a medical physicist at M.D. Anderson Cancer Center in Houston. I work in the Radiation Oncology Department there. And I'm here on behalf of the American Society for Therapeutic Radiation Oncology, ASTRO, to talk to you about ASTRO's position and interests on some of the things we've been hearing about today.

ASTRO is the largest radiation oncology society in the world. Virtually, all radiation oncologists in the U.S. are members but there are many

international members as well. So all together, there are 8,500 of us including medical physicists, radiobiologists who play a very important role in radiation oncology and also oncology nurses who come to ASTRO for educational opportunities.

And you'll hear some similarities between this presentation and Pam's a moment ago because radiation oncology and radiology work very closely together and have many of the same interests. And of course, ASTRO's principal interest is advancing patient care by providing access to radiation oncology and assuring the best possible treatment.

Now I was interested to hear the comments about patient education because one of the issues for radiation oncology is misconceptions on the part of patients, members of the public, even referring physicians who don't always understand how radiation can be beneficial when they believe all these statements. So public education is certainly an issue for ASTRO.

In terms of regulations, again ASTRO's primary goal is ensuring that patients who need

radiation therapy can get it. So while regulations have a very important role in assuring consistency and quality, we have to be careful that they don't inhibit access to procedures and to the development of new techniques.

So listed here are the agencies you're all familiar with that already play some role in regulating radiation oncology, the NRC of course, especially for radioactive sources, the FDA. While the MQSA doesn't affect radiation oncology directly, that is a source of referrals. So good mammography is important. OSHA regulations play a part.

IAEA standards haven't been mentioned this morning, I don't believe, and play a role in radiation oncology even in the U.S. even though they principally apply outside the U.S. A number of American physicists and physicians contribute to the development of those standards. So they have a way of working back into our own standards here.

NCRP provides important guidance to the practice of radiation oncology and the design of facilities. We've already talked about the state

agencies and of course, institutions have their own internal regulations all of which contribute to regulations affecting radiation oncology.

Now in terms of standards, we mentioned IEC standards several times today. Certainly, they can play an important role. But I do agree with Bob Morton that we have to take leadership to make sure that they are current and relevant particularly if we're going to consider adopting those or referencing IEC standards in the U.S. which putting my IEC hat on I think would be a great idea.

I want to mention IHE and particularly IHE-RO, the Radiation Oncology version of Integrating the Health Care Enterprise. This is an important and very exciting development in our field that will enable radiation oncology equipment and practitioners to communicate, transfer data effectively and seamlessly. This is critical of course all through medicine but very much so in radiation oncology which is probably the most technical and most quantitative field of medicine I'm familiar with. So we deal with large amounts of data and transporting those data

accurately is critical.

Some of the issues and concerns for ASTRO are monitoring. Monitoring is important but as already has been said, it will be most effective if it's consistent among agencies and if areas of duplication can be eliminated.

Regulations should be targeted to the need and require being updated regularly. To keep them focused on new equipment and new procedures.

We certainly need information about adverse events, equipment problems but also successful methods of treatment which must be disseminated. We have good techniques for distributing scientific information. We don't do so well about adverse events partly because of the threat of litigation and partly because we don't have a uniform, straightforward way of reporting adverse events, equipment problems in particular.

Quality of procedures must be maintained and regulations must not be allowed to inhibit or adversely affect the quality of those procedures.

Finally, with regard to public education,

we're certainly supportive of CDRH plans to coordinate education in this area and to enhance existing training opportunities while developing new ones.

I want to point out ASTRO's educational programs in this area. ASTRO has a number of activities going on including our Train-The-Trainer courses which is a very effective way of disseminating information and expertise rapidly. Radiation incident management course that is available and may be suitable for adoption in other areas and the radiation emergency planning training prepared by ASTRO which also might be appropriate for other groups. I will end there. Thank you very much.

FACILITATOR LESLIE: Thank you. Any questions for Geoff? Okay. Great. Thank you. Tom Kerr up next, the Conference of Radiation Control Program Directors. Sir, are you ready? All right.

MR. KERR: Good afternoon, everybody. It's good to be here. If I seem just a little down, it's not because of lunch. It's because this morning I got the call that I've been passed over again as a Supreme Court nominee.

Anyway, I'm the Executive Director of the Conference of Radiation Control Program Directors. So I'll keep my day job for a little while I guess and talk to you a little bit. I guess I'm the first speaker other than the FDA folks who actually works in a group that has some regulatory authority of its members. So this will be maybe a slightly different take on things. But CRCPD and CDRH have been working for many years, over 30 years, together to further the cause of radiation protection. We'll talk a little bit about that.

First off, we were established in 1968. It's a nonprofit organization incorporated in Kentucky not for any particular reason but other than the fact that the first executive director lived there. But it's a really nice place to be incorporated out of. Our members, we have a little less than 1,000 members. I don't think we're the largest group of anything. You've heard that a couple times today. But we only have about 1,000 members but there are a lot of states. All the states are represented as radiation control program directors and many of the state

officials and local officials as well as others that are interested in radiation issues are member of CRCPD. So although it may be small, it's really high quality folks.

Our purpose is important. We provide a common forum for the exchange of information among state and local radiation control programs and keeping the conversation going with the Federal Government on radiation protection issues as well. That's a real important part of our overall purpose because, and I heard this referred to once this morning at least, it's one of the things that CRCPD does is tries to promote consistency in addressing and resolving radiation protection issues. That's a tough job when you have 50 states and a couple of territories pulling in that many different directions. Also part of the mission is to encourage high standards of quality and to provide leadership in radiation safety and education. So we have many of the same goals that CDRH does.

The ultimate goal is to keep the radiation exposure of the patient and worker and general public

to the lowest practical level while not restricting the beneficial uses of radiation and radioactive materials because CRCPD covers a lot more than just the issues that CDRH might be interested in. A whole gambit of other issues.

This is what the org looks like. In particular, the two sections I would like to refer you to are on your left there. We have councils underneath our board of directors. We have the one that pays a lot of attention to issues in this area. It's the Healing Arts Council. That's composed of many different committees that look at all of these different issues and produce guidance, white papers, analyses, comments on different regulations and guidance that other groups put out. That's a real important part of what we do is under the Healing Arts Council.

And if you have any questions on the Healing Arts Council, I happen to have the Healing Arts Council chairperson in the room here and he knows everything. That's John Winston from Pennsylvania. He knows everything about that. Personally, I

wouldn't like that. It would take all the mystery out of life.

The second one that I want to point out for you is what's called the Suggested State Regulations Council. This is one that's very important because one of the major products that CRCPD works on is called the Suggested State Regulations. This is a comprehensive compendium of regulations that states can then take, change to their own circumstances. These are developed through committee action and advisors and resource persons work on these.

They go through an extensive review process, input from stakeholders and so forth just like regular rulemakings do just about and they go through that. They're produced. They are approved by the board for dissemination for peer review. They go through peer review at the federal agency level.

So when it comes out and it's ultimately approved, it's a pretty good document. We look at the Federal regulations. We look at particular things that are important to the states and those are

incorporated into the suggested state regulation. They address a lot of different issues, pretty much the entire gambit of issues that you might find in radiation control programs. That's one of our big ones. Those two I wanted to point out in particular because those are real important products for us.

One of the things that CDRH asked us was what issues needed to be addressed and I figured that being a little bit later in the day that the medical issues had been pretty much beaten to death and I think I'm right. We're not saying that those aren't important. I would refer to you all of those that the states are indeed very interested in CT and PET and fluoroscopy and all of the other medical things. But I thought that by this time we've pretty much talked about those and those are issues and we all know that those are issues that need to be addressed.

So I wanted to mention a couple that I didn't think would be mentioned quite so much by this time and that's some of the non ionizing radiation technologies like lasers and tanning beds. States are interested in those. We do have suggested state

regulations regarding those issues. So those should not be forgotten.

We also wanted to point out the non medical uses of ionizing radiation and those were mentioned briefly this morning like people scanners at prisons, baggage scanners and those kinds of things. Those are also issues that are of concern to some states.

One that was brought up by another state regulator that's here today and I'll refer this one to him if you have any questions is the criteria for electronic signatories for diagnostic and therapeutic procedure prescriptions. One of the things that we're seeing in several states is that there's really no set criteria as to what's accepted there. Many states require a written prescription. What does that mean in the era of electronic signatures? Even our own suggested state regulations talk about written prescriptions. So we all need to think about those things as the technologies advance how do we incorporate those kinds of requirements into regulations to allow the flexibility that we're

beginning to see in these areas.

A couple of other things. Many of the states are expressing some levels of concern about the cutting back on calibration of equipment. That remains an issue. I'm not going to suggest any solutions here but that is an issue that needs to be addressed. It needs to be very carefully thought through and I know that we've talked to some of these CDRH folks and they are thinking that through.

Also the need for training that's similar to the level two x-ray inspector training. If that kind of training can continue, that would be a very large plus from the states' standpoint, from the inspectors' standpoint.

In particular, one of the things we wanted to comment on was under monitoring on the plan is to encourage CDRH to continue harvesting data from outside sources. For example, the NEXT data collection and publishing may be that there needs to be some tweaks. It may need to be other topics that are addressed in the same way. But the NEXT data is viewed by the states as being extremely valuable and

should continue in some way.

Under education, we want to encourage CDRH to continue to provide that kind of training in conjunction with our annual meeting, our annual national Conference on Radiation Control as well as standalone forums. We've had a partnership for many years and this has been very effective. So we would just like to encourage CDRH to continue to work with us on that.

Also at our annual national conference, I would be remiss if I didn't mention the fact that ACR, AAPM, Society of Nuclear Medicine, ASRT, all work with us very closely to put on some really excellent training each year and I would like to make sure I mention them as well. It adds tremendous value to the national conference.

How we see ourselves as being able to help, CRCDP is a standard setting organization. So we do develop, as I said earlier, the coordinated set of suggested state regulations and the other guidance documents that go with them and we would say we will continue to do that. We're willing to continue to

work with CDRH to improve that process.

Over the last couple of years, there's been some streamlining of that process so that those suggested state regulations can go through more quickly. They had been taking two, three, sometimes more years to do that. But there is an abbreviated process that works very well on those. So we would be more than happy to continue to work on those and make that a very useful product for the states and the federal agencies.

We also assist in the collection and publishing of NEXT data and other specialty surveys. You would be surprised, you might not be surprised, how often I get called what are the states, how many states do this, how many states do that, that kind of thing and would you ask the states if they collect this kind of information. And every time, I'm thinking "Wow. I have to go out to each state." They just get surveyed to death, speaking from a state perspective as well. They just get surveyed to death. So we need to make sure that surveys that we do are focused and useful and aren't too burdensome from a

state standpoint because they like everybody else get too many surveys come at them from too many different directions. But we do that. We do collect that information. We publish the NEXT data and we'd like to continue to do that sort of thing.

And education, that's probably the longest part of our partnership with CDRH, high quality training of state personnel. Generally, we do that in conjunction with the national conference on radiation control. But there are other ways that we might be able to deliver that more effectively. Maybe we should look at regional models, smaller things, taking the training to the place of use, those kinds of things. I think there are some efficiencies that might be looked at in education that would be beneficial for all. So we would be happy to continue to work with CDRH on things like that.

I just wanted to point out one thing. Next week is National Radiation Protection Professionals Week and that's partly in commemoration of the discovery of x-rays on November 8, 1895. So this is the 110 anniversary. We want to make sure

that you all know that and celebrate that. This year's slogan. So we want you to turn to your neighbor here. That's all I have. But do remember that these folks work hard on your behalf and on each other's behalf and show the appreciation next week in particular. Thanks.

FACILITATOR LESLIE: Give him a hand. Thank you, Tom. John, did you have a question?

MR. KERR: This is the hard part.

DEPUTY DIRECTOR McCROHAN: I'm in the midst of this euphoria having gotten through my presentations this morning. I had a couple of questions and the first thing was could you comment in general on the background of the folks in the state programs because I think it's relevant for the conversation about training. We've heard from the medical societies today as well as the medical physicists and the radiologic technologists and I'm not sure that people have a good sense of where the state radiation control program people would fit in that spectrum in terms of the training they might already have had.

I noticed that there were a number of groups that talked about training and what they might be able to do. You made the point about regionalizing training opportunities as well as doing them at national meetings and so forth. I'm aware of the fact that we are certainly doing at the Center much less direct training than we used to do. I don't think it was entirely my fault. But I got to Center or the Bureau at the time just about the time they stopped doing direct training. I don't think it was anything about my arrival.

But we've done relatively little of that over the years and I think that there is a, or perceived to be, lack of opportunity for people in the states and certainly for even people in FDA to get access to appropriate training. So I guess the first question is where are people starting from and what's your sense of what the opportunities are.

MR. KERR: Like any other group, they are probably pretty diverse, probably more diverse than most of the societies here who have a lot of doctors and nurses and things like that. I think most of the

state programs are having a lot of difficulty in recruiting. A lot of the folks are straight out of college, have had some minimal training in that regard. I don't think you're going to find a lot of health physicists for instance because the states just don't compete with the private sector in terms of funding.

I'll think you'll find a fairly good concentration of military-trained folks for instance. I'm a Navy reactor operator on a submarine. I'm kind of typical of who might come out, those kinds of things. But a lot of times, I think it's true for a lot of states that the folks that are coming in the door have very little background in the areas that they will be working with and inspecting and the training that they get when they come to the state is in many cases I think probably the extent of the training they might have. So it's really important to have those basic introductory kinds of training and ongoing training to improve the quality of staff abilities.

DEPUTY DIRECTOR McCROHAN: I would just

add to that. I think that in the medical area I know that certainly some of the states personnel are former radiologic technologists but that may not be broadly the case.

MR. KERR: Right.

DEPUTY DIRECTOR McCROHAN: I think that it's one thing to know the physics if you will, however you get that training. I think it's another thing to appreciate the clinical environment in which that physics is operating, the machine and so forth. If we're talking about use problems, then I think some of that more clinical training or at least an understanding of that clinical environment and the applications and so forth is important.

MR. KERR: I know speaking for myself like I said coming from a Navy reactor background how to go fast and dive deep but the clinical stuff is beyond me. I guess I could get into brachytherapy and get into the dive deep part anyway.

DEPUTY DIRECTOR McCROHAN: Yes. The other question I had related to the Nationwide Evaluation of X-ray Trends Program. You've said and a number of

others have said on other occasions to me that NEXT is something which the states consider to be very important and I know that they've been an indispensable part of that program in terms of their participation in collecting the data. I know that the conference has been a partner for a long time in terms of disseminating the data.

But the question I have really goes more to the question of how is that data being used and applied. We have limited as it may be a picture of what the chest exam has looked like every few years for a number of years back, abdomen exams and so on and so forth. What I'm not sure is whether that data, that information, is being used by the states and penetrating into the clinical facility and having some impact there or if for all of these years we've been running this program and producing nice graphs that look good in publication but haven't been getting to what we really wanted to do which is influencing behavior on the ground. So I didn't know if you had any thoughts on that.

MR. KERR: I don't have a real good sense

of that yet. I'm new enough to this field that there are other folks in the room that would be able to address that much more, maybe John Winston or Don Flater from Iowa or Renee Fizer from Maryland who I think is going to be up next. They might be able to address that one a little bit more as to how exactly the states use it and the utility of it. But I know that there are certainly improvements that can be made in the process to make the collection more timely, to make the dissemination more timely for instance. Are you going to address that, John?

MR. WINSTON: Sure.

MR. KERR: You're not going to ask me a question, are you?

MR. WINSTON: No.

MR. KERR: You're not supposed to do that. You're not supposed to shoot me in the back.

MR. WINSTON: No, I'm just going to say I'm John Winston from Pennsylvania, Healing Arts Council Chair, and I don't have a clue.

MR. KERR: You don't have a clue.

FACILITATOR LESLIE: That's a straight

answer, isn't it?

MR. WINSTON: I think to follow up on two of John's comments. First off, like in Pennsylvania, our entry level positions, you can not qualify if you're a registered technologist. But if you have so many years in nuclear power or something like that, you qualify. That's where the training that CDRH has on x-ray really helps our inspectors because as far as I know, there really aren't any other sources for that kind of training, the hands-on training.

The other question with regard to the NEXT values, we use those as what are called reference values in the states where we make recommendations. There are states that actually set regulations which I don't necessarily agree with but set regulations for maximum exposures for certain projections. But I think most states do use those NEXT values for facilities with keeping their exposures as low are reasonably achievable.

MR. KERR: Thanks.

FACILITATOR LESLIE: Thanks. Cool. Next up we have two state presentations, Maryland first and

then the State of Washington. Renee Fizer is going to do the Maryland pinch-hitting.

MS. FIZER: Good afternoon. First off, thanks to FDA for allowing us to come and talk as a state program and, no, I am not Roland Fletcher. My name is Renee Fizer. I am Division Chief of the Radiation Machines Division at the Maryland Department of the Environment. I do apologize to you all because this is also the first time I will see this presentation today.

Just quickly a brief overview of our -- Oh, he has all of these things going. For those of you who know Roland, he usually sings his presentation or has it in rhyme or has a joke throughout the whole thing and I'm not going to do any of that. The Radiological Health Program is in the Department of the Environment. There are three administrations in the Department of the Environment, Wastewater, and we are the "R" in ARMA. Otherwise, it would be AMA. So we're hidden in an environmental department.

What this means is that we have what's considered a split program, meaning the licensing of

the physicians, the RTs, the therapists, is all done through a totally different department through a different set of regulations. In Maryland, it's the Department of Health and Mental Hygiene either through their Board of Physicians Quality Assurance, through their Board of Dental Examiners, Chiropractic Board, what have you. Our program strictly regulates the facilities that have x-ray equipment.

We've been an agreement state since 1971. We have, I'm guessing on this number, about 600 to 700 licenses at this point in time. We are now implementing our general licensing program. The fees are in place. We are putting together all the other stuff now to meet that requirement. In the RAM program, there are three permit writers, four inspectors and a division chief.

Radiation machines, we permit approximately 5,000 facilities that have x-ray equipment. That's hospitals, mammo, industrial, research, academic. About 12,000 tubes. I have one permit writer so I have two other vacancies. I have six inspectors and there's me.

In order to meet our statutory requirements, we do work very hard to have a cooperative working relationship with our Maryland stakeholders. So we definitely applaud FDA for doing a venue of this type and soliciting information about their changes upcoming.

Aside for registering the facilities with the equipment, we also have what's called a third party inspector system, our inspector program. We license medical physicists, other people who meet the education criteria to perform state certifications for most of our Maryland facilities.

We also regulate and register all the service providers that do any work in Maryland. Any company that installs equipment, performs maintenance on equipment, removes equipment, sells chemistry for conventional processing, they have to registered with our program and with our private inspectors and service providers, we meet with them at least once a year, the private inspectors twice a year. We send out newsletters. We have a little flyers. We work very close with them and they've actually been of

great value for us on making our program more efficient and more realistic based on all the other cutbacks going on.

The last item about -- I didn't realize it was blank. I'm so sorry. I have to look back here. And the last think is we do have annual fees that we collect from Maryland stakeholders. These do go into a special fund as opposed to a general fund. This year is our first year of having to subsidize our entire program only on special funds and it will be interesting to see what our senior management does in future years because we're not going to be able to survive very long.

I have to be honest. I wasn't really sure what this slide meant. So we're going on. The last thing that the staff does is we do respond to emergency response drills, graded scenarios. We have two power plants that we do the annual FEMA graded exercise. One is Calvert Cliffs and the other one is in Pennsylvania. It's Peach Bottom. So our guys are on call. We do do these things. We work with the counties, etc.

Issues and problems that we believe impact health and need to be addressed. A lot of these things have already been discussed in a great deal of detail. So I'm just going to gloss some of those. Fluoro, the high dose hitters, therapy, CT and thanks to the FDA we now deal with dental CT. Thank you.

Operator qualifications and end use is a very large and again remember. We're not a medical based program. So we're coming up some very creative ways to try to deal with some of the operator enduser issues and we'd love some input on that. I added to this also some non, perhaps, public issues but state staffing. It was just mentioned by Tom Kerr and John McCrohan. I have vacancies I can't fill because we don't pay enough. It's really hard.

The fee issue, like I mentioned the first year without general funds, it's going to be tight. The education issues. I have a degree in biology. I studied trees. I was a radiochemist at a public utility for six years. Now I'm in charge of a x-ray program. Most of my staff either have engineering degrees or masters in public health or environmental

hygiene of some sort. We don't have any RTs on staff. Again, we're more on the machine side of it but the training that the FDA has provided in the past and we hope that they embellish on in the future is vital to us being able to efficiently regulate the stakeholders and provide them the guidance that they need on reducing worker and patient dose.

Misadministrations, we've been doing some work in Maryland and we'd love to have some eventual federal help with this. Ninety-five percent of the reported external B-misadministrations are wrong patient. It's just gross procedural breakdown. Sometimes when we're dealing with these issues, we feel like we're working without a net. That's why we would like some support perhaps in the future. We're working right now. We have a plan for misadministrations. We're working with the stakeholders to identify the issues and come up with some reasonable responses to it.

The ESE, we've already mentioned that. I also agree with John that perhaps the NEXT data should not go into regulations. However, it is a wonderful

tool to have when you're troubleshooting a facility. It is marvelous and unfortunately in Maryland, we don't have a quality assurance program that's of any real value right now. We're now getting into a position where we're getting ready to pursue and adopt something and again those values every year that it comes out and the information is updated is of great value to us to be able to take back to our stakeholders and work with them on reducing worker and patient dose.

There is a concern to make sure that the regulations should be consistent whether federal or state and should not be nonexistent. One thing with the fluoro, fluoro is not on this list because we just recently put together a regulation package and it's basically a big awareness campaign and we used CRCPD's H-22 Committee. It was a task force on fluoroscopy. They developed some suggested state regs for privileging of in-house of fluoro users. We worked for three years with our Maryland stakeholders on appropriate language. Intent of the regs, we implemented those. They were published in June and

they actually become effective on December 31. For the most part, they have been very well received by our stakeholders because of the intent of the whole process there.

It's already been talked about that the technology is quickly changing and the State of Maryland would actually like to see one federal agency with regards to ionizing radiation perhaps in control of other federal agencies. It is a big issue for states. What goes on on Federal property is what goes on on Federal property. But when the members of the general public start getting involved, the Federal agencies aren't usually the easiest way for them to communicate their concerns. They go to the state agencies. So we get a lot of questions, comments when it's members of the general public being involved in nonmedical use of ionizing radiation and we would welcome the role of FDA perhaps of looking into that.

Consistency again with the state programs. For instance, there are at least two other Federal agencies that have dose to general public standards if there's going to be that type of thing. Again, we've

already talked about the training. It's of great value and we look forward to assisting FDA in whatever way possible to get that to be something that occurs.

We hope that there is the U.S. Department of Health and Human Services Administration buy-in on this change for FDA and CDRH. We realize that perhaps radiation safety in the medical community and the industrial environment isn't as a high visibility as homeland security issue. However, we do believe that it has a much broader and complete impact on national population dose issues.

And lastly, we understand that it does take a long time for the FDA to change regulations. However, we do hope that they utilize guidance document or the public health advisories. It's very hard for me to go to senior management in a state agency and say this is a real big issue. We need to look at this as a state agency. Unless I have quantifiable data to say this is a big issue or unless there is perhaps something from a Federal agency hopefully not an oversight agency but a Federal agency saying this is a concern, it's very hard for me to go

and try to pursue changing regs or putting in place other processes if those items are not there even if it's not a change in regs.

One other thing to the FDA, and of course they're aware of this, is even though different states have different regulations, different authorities, they have fees, they don't have fees, big programs, small programs, a lot of states do have expertise and/or knowledge on a wide range of topics and it's just waiting to be garnered. Of course, that can be done through the CRCPD. We have great resources there on little pet projects that we've worked on that turn into wonderful blooming flowers that can be harvested.

I have a comment about a previous comment about the 2579s to the gentleman who had hoped that 2579s for replacement parts could be taken away. My comment to FDA is please don't do that. We have a regulation that any machine that has been previously owned and moved or refurbished or any time a major component other than a tube has been replaced, it has to be restate certified which is done through our program prior to use on patients and we find that more

often than not there are violations, functional violations, with the machine, image receptor issues, etc. on those machines and a lot of times the facilities don't let us know when these happen. The way we do find those out is by submittal of those 2579 forms. So it would be taking a tool away from us.

Lastly, Maryland agrees with and offers support and assistance during FDA's transition. This state perceives the benefit to our program as well as to the general public for the proposed changes. Thank you.

FACILITATOR LESLIE: Thank you, Renee. Well done. Okay. Ellen Haars from the State of Washington.

MS. HAARS: Good afternoon. I would like to thank the Food and Drug Administration for the opportunity to address its Radiological Health Program Plan. I also would like to compliment you for your organization for seeking comments from stakeholders with different perspectives.

Today I'd like to focus on who we are, the Washington X-Ray Program, our perspective of what are

the radiological health issues and you may have heard them already but you're going to hear them one more time, our perspective on the plan, our view of a partnership with FDA and the states and proposed next steps.

My message will have five key themes and these can be grouped into three major categories and those are training, guideline development and technical assistance. You're going to hear that throughout my message.

First of all, a snapshot of the State of Washington X-Ray Control Program. We have 58 registered radiation machine facilities. Fifty of those are mammo facilities. Over half of the facilities are dental. We have nine surveyors in the program, two certified MQSA surveyors and two in training.

A very important part is that over half of our surveyors will retire within the next five years. If you combine all the years of the staff, it's 255 years with a range from eight years to 37 years with the program. So that's good because they like the

program and they stay. But it's not so good because they're going to be leaving to retire.

The program is 100 percent fee supported. We have to charge the fees to cover the cost of the program. Of course, the registrants do not like that and I can understand why.

I want to emphasize the fact that we have an aging workforce in our program. We are looking at ways to reduce the weight of inspector equipment, smarter ways of handling the equipment. A 40 pound phantom presents a problem and finding qualified individuals to replace retirees also must be addressed. We need FDA's assistance in training new and current so that our workforce is well qualified to perform their job duties.

The current problems can be grouped into training, guideline development and technical assistance. Let's start with training. We want staff that are up-to-date and are well qualified. How do you test a C-arm unit? We need more information on CT systems and how to evaluate these systems now that they are so sophisticated.

We need training tools to help surveyors know what to look, what it means and what are the key findings. The state of course has a role in it. We cannot just depend on FDA for that. Course patterned after the FDA basic surveyors course is a good place to start.

Guideline development, another area of health issues. For example, give us guidelines regarding the ever-increasing radiation doses to medical patients due to the proliferation of high technical modalities. How much radiation is too much for diagnostic imaging?

Technical assistance, this is another category that needs to be addressed. Here are some examples of areas that we need assistance. The department recently received a letter from two medical physicists in the state reporting their data and observations concerning dose estimates for patients receiving CT scans. They found the typical head dose received in Washington State is higher than those published in the European studies. I want to incorporate their letter into this presentation

because we want to work with FDA on how to proceed.

I was also asked to give my general reaction to the radiological health plans. In these times of limited resources and demand for public accountability, it is important that government agencies are accountable, efficient, effective and doing the right thing. We support your vision statement, the shift to product use and we ask you to continue to provide technical assistance, share information and coordinate the members of the radiological health community.

However, we have several areas of concern and ask that you consider our suggestions. Your evaluation and accountability tools are not clear. Tools should be developed to demonstrate a performance review mechanism. The citizens need to have a clear, concise view of how this government program is working and whether the citizens are receiving value for their tax dollar. State regulatory agencies have a key role in the success of this program and your report says that. It is important therefore to recognize that funding is always an issue with the program. We are

100 percent fee supported and we may need assistance.

Then the next category you asked me to talk about was examples of partnership and here again, I'm going to give examples in training, guideline development and technical assistance. Your plan identified five major program elements: standards, monitoring, education, research and program. These elements are designed to protect the public from hazardous and unnecessary radiation while insuring appropriate use of radiation when necessary. We support your intention.

So how can we work together in training? In the next five years, over half of our surveyors will retire. We need a mechanism to insure all surveyors have adequate hands-on inspection training in the classroom and in the field. We need training that's similar to the basic course offered by FDA as well as on-going so that the current or existing staff are up-to-date.

Guideline development, here states and FDA can work together in collection of adverse events, dose and exposure data. The states can collect the

data as well as perhaps other parties and forward it to FDA and in consultation with the states, analyze the data and make recommendation and develop tools for sharing this information with regulators, consumers and device operators.

Technical assistance is another area where we can work with FDA assisting states and finding alternative survey tools or proposing other ways of doing business. What about the reintroduction of the old FDA high-low study or bringing back perhaps the modified but revisiting the old DENT program. We are only able to visit DENT just every five years. If we could have another tool in between which would not be equivalent to an inspection but it would be a screening tool for facilities that need to be looked at.

So what do we think should be the next step? Of course, I think we start with sharing the results or the summary of this meeting and identify any revisions to the plan. You should regularly share information about the plan's status and the outcome of evaluation and accountability tools with the

stakeholders, perhaps have an annual meeting where we get together just like we are doing today and lastly and most important is communicate, communicate, communicate. Don't just do it here. There is another Washington. I had to say that.

So one more time, I had three key things but they all fit into the three categories. We have an aging workforce with retirements pending. So we need hands-on training for new hires. We also need training for new modalities, field compliance testing. We ask that you emphasize dose reduction and improve image quality, produce culturally sensitive information for users and consumers, form partnerships with states on technical issues and have a performance review mechanism so that you can tell where you are and are you making progress. That concludes my presentation.

FACILITATOR LESLIE: Thank you, Ellen. Give her a hand. Any questions? Great. Thank you. John, were you heading to the mike?

DEPUTY DIRECTOR McCROHAN: Yes.

FACILITATOR LESLIE: Okay. I guess you're

not so fast.

MS. HAARS: You know they're waiting for break, don't you?

DEPUTY DIRECTOR McCROHAN: And they're all getting warm as I am. But I did want to ask a couple of questions. I didn't want to let Renee totally off the hook. But I guess that one of the things that would be perhaps useful for you to clarify, two things. One is with respect to the training. You mentioned a basic radiological health training which back in John Goforth's day before my time we used to do in what was then BRH and I think one of the things that perhaps this is less of a question and more of a comment for discussion tomorrow is I think that in the educational breakout sessions, one of the issues I would hope would be discussed is how can we deal with the fact that we have a regulatory community both state and I would say federal where the entry level positions are attractive to people who don't come prepared with the kinds of educational backgrounds that we might like.

MS. HAARS: It is unusual.

DEPUTY DIRECTOR McCROHAN: And then I think the consideration of given today's problems what sort of education do we want to provide to those people. Do we want it to be as it would have been in the old days if I may very machine oriented or do we need it to be a training which would prepare people better to provide oversight to facilities to assure that the facilities are meeting their responsibilities to do quality control and quality assurance and all of the things that I think everybody knows they ought to be doing? But I think what may be missing in some respects is the external agency looking and asking questions and so forth. From my point of view, it may be less about machines and therefore less of a physics orientation than used to be the case. But perhaps that's something that could be talked about tomorrow.

You mentioned dental. Renee mentioned dental and you're entirely welcome. We're happy to make your life more interesting by evidently having not terribly long ago approved on the medical device side of our house dental CT units that were I believe classified as though they were panoramic x-ray units.

Anyway, we'll talk about that I'm sure at some point.

MS. HAARS: You also approved a hand-held dental unit too.

DEPUTY DIRECTOR McCROHAN: We just want to do our best to make your lives more and more interesting.

MS. HAARS: Thank you.

DEPUTY DIRECTOR McCROHAN: But I think one of the things that others in the audience may not appreciate is the fact that I think you mentioned a figure which I understand is fairly typical where the number of x-ray tubes in Washington and I think in Maryland are about 50 percent dental tubes and about 50 percent medical tubes.

MS. FIZER: Seventy percent dental.

DEPUTY DIRECTOR McCROHAN: Seventy percent dental. Okay. Those dentists. Nobody here from the Dental Society I don't think. I think there's a question probably in some people's minds about what's the relative priority that ought to be given to dental versus medical when you think about what's being exposed and the degree of exposure and so on and so

forth, notwithstanding that we've complicated matters for you by approving hand-held units and CT units which have probably changed the picture a little bit at dental facilities. I'll let Renee come up and berate me more immediately.

MS. FIZER: In response to the Maryland program as I mentioned, we do have third party inspectors who do most of the medical equipment. My inspectors predominantly inspect dental, veterinary and mammography facilities. Our dental lobby, all of our requirements for dental machines including the inspection, frequency and fees are in our statute. They're not in regulation so that because of the issues in the past with I guess concerns about the dental lobby and the effect on the dentists.

But what we've done since 1999 is we've identified that in the dark room because of the dose issues, we were finding -- Let me back up. I'm sorry. Not very well prepared. We found that the as-found values for most of the intraoral machines were above those of the NEXT data. They were significantly above what the NEXT data had said the average national

ranges should be based on the KBP of the machine and the type of films, the D-speed versus at that time it was only E-speed was the only other option.

So we evaluated the profile of violations found and found that over 70 percent of the violations were in the dark room and they had to do with the processing. A lot of the facilities weren't changing out chemistry. They had disengaged their heater elements in the processors so to try to prolong the life and the way they compensated for light films was turning up the exposure times for the patients. So we identified a statewide population dose issue even though we're talking about dental here.

We decided especially since that's what our inspectors do are the dents and the vets we would address this. So we spent two and a half to three years working with our dental lobby, the Maryland State Dental Association, and giving over 20 outreach presentations talking about processor issues, dark room issues. Fog was another big thing. We sent out flyers.

We put together a regulatory packet. We

didn't change the regs. We put together a booklet that had all of the regulations that concerned the dentists into one little thing because as most of you all know, the suggested state regs or most of the state regs are 600 pages long if you include all of them. So it's really hard to wiggle through those.

We worked with our dental lobby on putting together that packet and half the page was the legalese and the other half was what it meant. We wanted to put little Mr. Tooth things in there and gold stars but they didn't like that. So we worked with them a whole bunch and we've been actually able to drop the as-found settings and right now, I'm pulling ten years of data. I'm having to do it manually because we up until three years ago didn't have an electronic system for reporting dental inspection information. So I'm pulling it file by file back from 1995. Because what we're hoping to show is a drop-in population dose based on the as-found conditions based on KBP and the type of film that was used at the time of the inspection at the facility.

The other thing that we did was we identified some controversial topics. We put together a little task force to look at premixed auto processor chemicals. We called together a couple of the manufacturers of film, the auto processors, dental auto processors and the companies that manufactured the auto processor fluids, the premixed fluids because we have a minimum optimal density speed criteria in Maryland and we believe that there were some of these premixed dental chemicals that when they were fresh out of the bucket, they opened up a can, they could not meet the processing requirements.

So we met with a couple of the large nationals of the film, the equipment as well as the chemicals and discussed this. We also had the Maryland State Dental Association involved as well as the Commonwealth of Pennsylvania. New Jersey radiation programs were also involved on this. And we discussed these issues and we brought up some things like for instance there is no expiration date on the bottles of these premixed chemicals for the facilities to use as an indicator of how old it is, a lot of

other issues as well with that.

But we're in the process of trying to address those. We'd like to see a drop in the population dose and I forgot what the original question was now. But we're looking at things. Thank you.

DEPUTY DIRECTOR McCROHAN: I'm sorry to keep you stuck up there. I think it's just interesting to realize in the predigital age and frankly most of the community out there is still in that age where we're talking about film as the image receptor, there are lots of things that are not related to the electronic product per se that affect the exposure to the patient and as Renee said, certainly the film that's selected and the chemistry and the processing of that film have an effect on the exposure.

I think that now things are becoming more digital is an inclination to think that those problems have gone away and in substances, that's probably true. But I think additional, newer problems are coming in in the sense that unlike when we have film

as the image receptor and if you make it totally black, the person reading the film is probably not going to like it very much and send you back to do it over again.

With a digital image receptor if you use more radiation than you needed to get the clinical image, you still get a very nice clinical image. In fact, you might get a quieter, smoother image than you would otherwise have gotten even though you might have used a dose that's far in excess of what you would have needed to get the clinical information.

But just a comment. One other quick point. Renee mentioned misadministration in therapy presumably with a machine based source and we had left Geoff off the hook earlier and I wondered if he could comment on whether or not in the machine based radiation therapy world the comparable sorts of quality control procedures and so on and so forth exist which are I think mandated in the isotope based therapy world by the regulations at NRC and the agreement states. I don't know where the states are in that and I don't believe there's any federal agency

with the authority to regulate use vis á vis therapy.

DR. IBBOT: I think that you're right that there is no federal agency at the moment dealing with this. There are publications and recommendations for groups such as the AAPM, the ACR and ASTRO giving recommendations for quality assurance procedures that I think are every bit as thorough and probably more extensive than the previous advice for isotope units.

Some states have adopted potions of these recommendations into regulations. Some have gone much further with that than we would like because some of these publications were intended strictly as recommendations for departments, institutions to consider in developing their own QA programs. So there's a broad range of degrees to which publications like that have been adopted into regulations but there is certainly much more uniformity in the degree to which the QA recommendations have been adopted into clinical practice and for the most part, they are followed.

In fact, I will step to one side and put on my RPC hat and tell you that on our visits to

radiation therapy departments while we often find some small aspect or other that we don't think is being addressed in a quality assurance program, for the most part institutions we visit are following the guidance of groups like AAPM quite closely.

FACILITATOR LESLIE: Good. Thank you, Geoff.

MR. WILLIAMSON: My name is Steve Williamson. I'm the Section Chief of X-Ray and Accelerators in the State of Pennsylvania. I just wanted to reiterate and agree with Marilyn and Washington on some of the issues. The State of Pennsylvania, the VRP is 100 funded. We also have an aging inspector staff and they rely a lot on the -- I had a lunch discussion about a lot of this stuff as far as Level Two training as far as which really adds to the inspector training. We really want to know what's going to happen with that. Our Level Two agreement ends in 2007 with the FDA.

Reiterate the 2579 forms that we use with all the vendors. We've currently started registering all the vendors in the State of Pennsylvania that

supply equipment in the State of Pennsylvania. That more or less works as a triangle for our organization, the VRP, the vendors and the registrants. We tie all that together into one thing to know what equipment's coming into the state and being installed and new equipment coming online, what the inspectors are faced with when they go out to do inspections and also the vendors as far as providing a lot of information back and forth.

The MQSA changes as far as the acceptability of survey equipment is another big item for us. We're looking at new equipment to purchase in Pennsylvania. We'd like to have some guidance maybe from the FDA on that as far as what is acceptable equipment, what they're going to consider acceptable or if they're even going to give us any acceptable criteria. Pretty much to tie in with a lot of new technology, the new equipment and the new instrumentation, I think there needs to be a lot of cooperative effort on that between the FDA and the states on a lot of that to continue the programs we have.

FACILITATOR LESLIE: Cool. Thank you. It's already hot in here. So I want to take a break. Two quick things. One is a couple of you in the restaurant apparently got up and out of there without paying for lunch. I can just envision you were in the middle of a conversation and just got up and walked out. So if you would be kind enough to sort that with the dining room manager.

Second thing is one of the things I want to make a little time to do this afternoon is inquire about what you mean when you talk about collaboration and partnership as we've had this thing going forward. I'm really going to be interested to hear what you think collaboration and working as partners ought to be, how high the bar should be set.

On one hand, your 16-year-old would say collaboration is just fine when you hand them the car keys and don't ask where they're going. That might not pass your test. There are those that would say collaboration is that I will comply grudgingly with a Supreme Court decision. That's probably not an answer either. There's another one that say I won't go

anywhere without you.

So I'm really interested in hearing a variety of you talk about what does collaboration mean, what does working together mean, from your various positions as we go forward. I'll make a little time on the agenda for that. Let's reconvene at 3:05 p.m. That will give you enough time to get some coffee. I think there may be cookies. 3:05 p.m.

(Whereupon, the foregoing matter went off the record at 2:37 p.m. and went back on the record at 3:07 p.m.)

FACILITATOR LESLIE: As they say, come on down. All right. If we could, I'd like to get started. Could I have your attention? We have three things left on the agenda this afternoon. Two are already on your agenda and one I've taken the audacity to add. The first thing is the public comment period which I want to begin here in just a few minutes. The second is to inquire your views on the nature of collaboration as you think it should be, could be, ought to be in this RAD Health Program and the third piece is whatever words that I'll say that set up the

day tomorrow.

Now I have taken the liberty of moving the microphone from back there to up here because I noticed that those of you who spoke were having to speak with your back to half or more of the audience and I thought you probably didn't like that anymore than the rest did. So we've just for this part moved it up here in front so you can at least speak to your colleagues.

For public comment, let me get into the public comment. Let me just decree that part of meeting open and in that regard, anyone who would like to speak can certainly do so. This meeting was published in the *Federal Register* so that anybody that would like to speak can actually do so and two parts to that. One is if there are things that you'd like to say from the microphone that's fine. If they're either in addition to that or separate from that, you're certainly welcome to submit to John and his staff for inclusion in the record. That can be handled either way that suits you.

I have at the moment seven names on the

list, some of which signed up ahead of time for that and I would take those in this order that you signed up and after that it will be first come, first served when everyone's had everything they wanted to say about that or we've spent an hour on it. We'll shift into the next part.

So the list that I have at the moment: David Lytle, Jim Shepherd, Steve Rohring, William Benner, Dr. Sandra Read, Liz Coronado. If you don't mind I'll go in that order. Then anyone else after that I see some of you smiling. Did I misspeak somehow or another? What did I do wrong? Lisa, sorry. Okay. David Lytle first. I think the original thought was three or four minutes each. Does that work for you? If you need something different than that, talk to me.

MR. LYTLE: It works for me. I'm David Lytle. I'm the Executive Director of the International Laser Display Association. We're a little different than everyone else here. Our members, their goal is to have fun with radiation. They make laser light shows for artistic and

entertainment purposes.

And you all know that the responsibility of making fun is not easily born. We started doing shows in the mid 70s and the Bureau of Radiological Health back then immediately enacted a series of regulations to protect the public and they really stepped in. They saw a need to control some of these exposures and enacted many regulations that worked very well back then.

But now we're fast-forwarding 30 years in the future and we're so glad to have this opportunity because many of those rules that worked then don't work now. I'll give it in a nutshell. What our industry faces that a lot of you may not face is a requirement not only to comply with all the usual bells and whistles that all the laser products must comply with but we have to submit a variance requirement if any of our lasers are above 5 milliwatts and we have to submit a specific request to vary from the standard to use this for an entertainment application and that has to be approved by the CDRH before the product can be brought to

market.

The second step is if our customer wants to purchase this product which has a variance, they cannot purchase the product. The customer then has to submit a request to the CDRH to vary from the standard to simply buy the product and they have to wait until that's approved before they can take delivery of the product.

Then finally before they can use the product, they have a file a laser light show report with the CDRH defining the proper use of the product and that's because the CDRH defined a laser show as a product and they actually control the use of the product in that regard. I've just learned that's a pretty unusual situation here. But that's the fact of life of us.

In now 2005, the U.S. industry as changed in many ways, most of them for the worst, the current regulations have built in a huge amount of uncertainty because there's no guarantee of when or even if our variances will be granted. The customer sees that and they're not inclined to hop into a competitive

marketplace when they don't even know if they can get the product.

Manufacturers in turn have a big disincentive to product new products especially if they're cutting edge or if they have a novel approach because there is not guarantee when or if the CDRH will approve that variance. That's not knock on the CDRH. It's a knock on the fact that their resources are limited and we're perhaps low on their radar screen. There are many other applications, but as a consequence, the U.S. laser industry has suffered immensely. Our market share has declined incredibly. It's to the point where our association will probably not have another conference in the United State because it's too difficult to stage laser shows here and most of our members too difficult for them to bring their products to a trade show to just show them to potential customers.

So it comes down to what we can do about this. We have a written proposal we submitted to the CDRH which proposes to streamline some of these reporting burdens. So that instead of doing a

variance for every single laser product, most of which are very similar and are no novel uses, nothing different about it, to eliminate that requirement to focus their resources only on the applications which pose the greatest risks.

That might be something which wants to change the exposure levels to the audience or route the show in a whole unique way. Those will pose risks and those deserve attention. But 99 percent of the shows done today in the U.S. and for the last 25 years have a record where they don't need to do that. So we're proposing to eliminate that reporting requirement.

We're also proposing since we want to get down to the use of the product let's have a collaboration with the CDRH and produce training materials, safety materials, to provide to that enduser that they can know how to produce this show effectively and safely. So instead of asking them to fill out a pile of paperwork which is dense to them, it's practically grief, they have no idea really what it means, we'll give them safety information, safety

training opportunities saying this is how you use the product, this is the proper method to use. We think that will encourage more compliance and will enhance the overall safety levels of the shows while at the same time making it easier for companies to manufacture and sell the products and making it easier for the CDRH to concentrate its resources on those that pose the greatest risk.

So that's our hope and talking about collaboration, our view is we want to work hand-in-hand with CDRH to develop these materials. We have no problem with the current exposure levels of bells and whistles. It's a matter of putting that into an effort which everyone can understand and digest easily enough. That's what we're extending our hand to do and we hope to do in the future. Thanks.

FACILITATOR LESLIE: Thank you. Jim Shepherd.

PARTICIPANT: They had to leave for an early flight. They can't deliver their speech but they have written comments.

FACILITATOR LESLIE: Okay. And we'll get

those.

PARTICIPANT: We have them.

FACILITATOR LESLIE: Got it. Okay. Steve Rohring. He has his coat off. Must be expecting it to get warm in here.

MR. ROHRING: I hate to read in front of people but I'm going to read our written comments for the record and then probably make a few comments of my own. In a sense, I've approached the age of 50 plus. I'd better use some help.

Thank you for the opportunity to address the Food and Drug Administration stakeholder meeting. My name is Steve Rohring. I'm here on behalf of the Federal Aviation Administration. I would like to thank the FDA for their assistance over the past ten years in addressing the impact of outdoor laser demonstrations on aviation.

When these shows began to proliferate in the mid 1990s, the FAA received reports of pilots being impacted by the inadvertent illumination of their cockpit by lasers. The FDA's Center for Devices and Radiologic Health and their regulatory role with

regard to lasers came to the aid of the FAA by requiring operators of outdoor laser demonstrations exceeding five milliwatts in power to notify the FAA in advance and resolve any objections that the FAA may have.

Since that time, other applications for the use of outdoor lasers and the number of uses of outdoor lasers has increased dramatically. As a result, the FAA now faces new threats to aviation safety and security related to the use of outdoor lasers.

These threats predominantly fall into two major categories. First, the outdoor use of high power, visible and nonvisible lasers for scientific research and commercial purposes has and continues to dramatically increase due to the emerging technology and the increased affordability of lasers. These lasers are emitted from the ground or airborne platforms and have the potential for devastating results on aviation. Currently, there is no regulatory requirement for these operators to notify the FAA of proposed outdoor laser operations. Some

notify the FAA voluntarily and many do not.

Second, over the past year, the FAA has received an alarming number of reports of apparently intentional illumination of cockpits by a variety of types of laser pointers hand-held and others. In fact, the FAA has received over 200 such reports since November of 2004. Although the vast majority of these incidents have not resulted in injury to pilots or passengers, some injuries have been reported and the FAA believes that the potential exists for even more devastating results.

We believe that this matter is crucial to aviation safety and security and ask that the FDA explore any means possible for assisting the FAA with this matter as long as the FAA remains willing to work with your staff to identify, develop and implement any measures that may mitigate the potentially harmful effects of the outdoor use of lasers.

We have had a lot of success in addressing outdoor laser light shows and since the 1990s, when there were some incidents in Las Vegas, those reports have literally dropped off with the variance process

and with the analysis the FAA has done when they're notified of laser operations.

We are now hearing reports though that many operators do not contact the FAA even for laser light shows. The laser light shows are only a part of what we're concerned with because there is now a lot of other high power outdoor lasers that are projected through the navigable airspace. Many of these lasers far exceed the five milliwatts. In fact, they are very powerful lasers and they're now not only shot straight up or straight down but they're projected at angles over the horizon which can affect a lot larger area of airspace.

So we're very much interested in some kind of a notification or control process that we can be aware of what's happening and being able to apply some standards to whether these would be safe and how we can integrate these lasers safety into the national airspace system.

By the way, there is also, I just learned in the past week, a House resolution that is reported out of committee approximately two weeks ago that

would actually levy a criminal fine for the use for laser pointer against an aircraft. So we'll see what happens with that in the future. Thank you.

FACILITATOR LESLIE: Great. Thank you. Mr. William Benner.

MR. BENNER: Both of these guys are going to be a hard act to follow. My colleague, David Lytle, from International Laser Display Association works within our realm of business and we've actually worked with SAEG-10 Committee on producing the document that light show people use when they file reports. My partner, Patrick Murphy, wrote most of the document that people use to file that.

My name is William Benner. I am President of Pangolin Laser Systems. Pangolin is the Microsoft of the laser light show industry. We produce software that people use to create their shows and like Microsoft, we have about 90 percent market share. We've been in business since 1986 and we have users in 60 countries. This position that we have gives us a unique view of the laser light show industry in that we can see how they're being used here in the U.S. and

abroad.

What I'm coming here to speak to you about is much like my colleague, David Lytle, spoke to you about. We've seen a tremendous decline in laser light shows here in the United States. Currently we sell only about eight percent of our software into the United States, not that another company sells more. But 92 percent of our business comes from Asia and Europe and Latin America. One reason for this decline in the U.S. use of laser shows is because of the variance requirements and the difficulty in conforming with current CDRH regulation.

Earlier today what we've heard is that the CDRH regulates only products, not the use of that product. Well, that's not exactly true because in 1976 what CDRH did was they called laser light shows a product and since that point in time, they require use to have a variance to sell the laser equipment. They require the venue to have a variance and they require a variance for the show itself.

Because as David Lytle said, we're kind of low on the totem pole, low on the radar of CDRH's

daily business, they're looking at CT, MR and various exposure levels like that, as a result, the time it takes us to have variance applications approved could be three months on the very early end and my company and another company has a variance request in that has been in for over a year and I think by law they have to approve them in a year. That's what I heard. Maybe I'm wrong.

So as you can see, it takes a very long time to get a variance approved even for companies like Pangolin who are very active in the safety community. We've attended ILSC. Obviously, we're here. We attended almost every SAEG 10 meeting. We produced the document FAA uses now to make sure that laser light shows are safe and yet here we go. Fourteen months after we've applied for a variance we still don't have it.

We've come here with a couple of suggestions. One of them is to relax the variance requirement, possibly substituting that for a reporting requirement just like laser manufacturers themselves need to produce what's called a Federal

Laser Product Report about their system to make sure that it meets the regulations. That sounds reasonable to me. Instead of us submitting paperwork and waiting for CDRH to look at the paperwork and then rubber-stamp it 14 months later, we could just submit the report and start using the show immediately.

Another suggestion that we have is to harmonize with IEC as much as possible. There are currently two IEC documents which regulate and control and describe how lasers are used safely, 60825-1 and -3. The -3 standard actually discusses how to do laser light shows safely. These are being used outside the United States obviously and as David Lytle says, laser light shows stem back as far as 30 years and we have an excellent safety record even outside the United States.

So we believe that by relaxing the variance requirement, substituting it for some sort of reporting measure and by adopting IEC we won't be giving up anything in terms of the excellent safety record we have. But instead what we'll have is a much more streamlined, much more uniform approach just as

taken all over the entire world and at the same time, what we realize is that we burden CDRH. You should see the paperwork that we submit to CDRH that somebody on the other end has to review.

We would like to take that and substitute it for some training as David Lytle said and I'm running out of gas here. But that's the gist of it. I look forward to working with CDRH and as far as my colleague says here "Ask not what you can do for your country but what your country could do for you." That's it.

Well, we're a software author. We write software all the time. If you need software to help us to submit these reports to you, we'll write it for nothing. We'll write it quickly. I'm serious. What do you want us to do? We'll do it. No problem. My partner, Patrick Murphy, spent a year and a half of his life working on the document that FAA uses. We are serious about laser safety because it's our business. If lasers bring down planes, guess who that's bad for? Ultimately, it's bad for us. So we've very serious about this. We look forward to

these kind of collaborations, training programs, whatever it takes. You tell us what you want. We'll make it happen.

FACILITATOR LESLIE: Good. Thank you. Dr. Sandra Read. Hi.

DR. READ: Thank you. I'm here to talk about a much more serious side of this committee. We've had so much fun listening to the laser talks. But I'm here to talk to you about the industry of the tanning industry. I am a dermatologist and I'm here to talk to you about the darker side of tanning.

Thank you for allowing me to have the opportunity to be here today and to speak to you about something that's of great importance to me and to all of you and the FDA which is the continued and further regulation of the indoor tanning equipment. My name is Dr. Sandra Read. I currently serve as the President of the D.C. Dermalogic Society and I'm speaking on behalf of the American Academy of Dermatology Association.

I am here to ask you to partner with the Academy to protect our patients and especially our

children from skin cancer. We ask that you do not decrease regulation and oversight of the indoor tanning industry. We ask you to encourage the FDA to institute a national age limit to decrease the exposure of minors to ultraviolet radiation by tanning salons.

The Academy of Dermatology strongly urges the FDA through its Radiological Health Program not only to continue to focus on the regulation of indoor tanning but the Academy would like to suggest that you increase the regulation of these devices. It is our concern that the reorganization plan that is being discussed today would actually divert needed resources from this missions.

According to 2005 and 2010 plan, the program will focus resources on the products and procedures with the highest risks to the public including those that are affected by the greatest numbers of people or cause the most severe problems. Indoor tanning equipment meets all of these criteria.

HHS in 2002 declared broad spectrum ultraviolet radiation to be a known carcinogen and

declared that exposure to sun beds and sun lamps to known to be a human carcinogen. It's based on sufficient evidence of carcinogenicity from studies in humans. As we are all aware, indoor tanning equipment emits broad spectrum ultraviolet radiation which again as HHS has declared is a known carcinogen. HHS even goes further in its tenth report on carcinogens to state that epidemiological studies have shown that exposure to sun lamps and sun beds is associated with skin cancer.

For the majority of users, indoor tanning equipment provides a cosmetic service, however one that can sadly lead to serious side effects. The long-term consequences of using indoor tanning equipment can lead to a lifetime of damage to the skin and eyes and in some cases, even be deadly.

Given our society's misplaced and destructive fascination with being tan, the use of indoor tanning equipment continues to grow and has become a multi-billion dollar a year industry which is putting more and more people at risk for developing skin cancer, eye damage and premature aging of the

skin through photo damage. What is even more frightening is the increasing numbers of preteens and teenage users of indoor tanning equipment which seems to be a contributing factor in the increased number of children and young adults that our members are treating for skin cancers including the deadly melanoma.

As you are probably aware, melanoma is the most aggressive form of skin cancer which will lead to death in one out of every five individuals diagnosed. I have been in private practice in Washington D.C. for more than 20 years and I've watched with horror in the growing popularity of the indoor tanning use especially among my younger patients. In my practice, I have had teenagers and young adult patients with skin cancers and melanoma. Some have died. Childhood melanoma is increasing.

Recent statistics show significant increases and this raises a red flag to dermatologists and all the medical profession and so it should with the FDA. Dr. John Strauss, a pediatric oncologist at Johns Hopkins University, coauthored a July 2005

article in the *Journal of Clinical Oncology*, stating that statistics gleaned from the NCI CyRE data show a dramatic rise in the rate of melanoma among children. The variable of greater exposure to UV radiation was listed as a factor in this increase.

Non melanoma skin cancer is also on the rise in our young patients. This was reported in *JAMA* August 10, 2005 by Dr. Christiansen et al. Dr. Christiansen is a dermatologic surgeon at the Mayo Clinic who treats the most advanced and the difficult of the skin cancer cases. In an interview, Dr. Christiansen also expressed concern over the causative association between intentional, intense, intermittent exposure which occurs in the tanning salon use.

That is why we are all here today to protect our patients who are not able to protect themselves. Much like restrictions on cigarette and alcohol consumption and access to firearms, our culture places great importance on protecting children from harmful products. The Academy has encouraged the FDA for many years to increase its oversight of indoor tanning equipment and has specifically requested a

revision of the current warning label to state an explicit link between UV radiation and skin cancer.

Now is not the time for the FDA to lessen its vigilance especially as medical science and data is revealing more and more about the adverse effects of ultraviolet exposure. Now is the time for the FDA to make protecting citizens from the dangers of indoor tanning a priority. It is a shame that our patients and particularly our children are dying to be beautiful.

For these reasons, the Academy strongly urges the FDA to make indoor tanning regulation a top priority of its radiological health program. I thank you for your time and attention.

FACILITATOR LESLIE: Thank you. Lisa Coronado.

MS. CORONADO: I think I'll follow her lead. Good afternoon. My name is Lisa Coronado. I'm a Senior Health Physicist at the National Institute of Health, Bethesda, Maryland. Today I'm speaking on behalf of the Health Physics Society. We're about 6,000 members strong and we are health physicists who

are specializing in the field of radiation safety in minimizing dose to be as low as reasonably achievable, also known as ALARA. My children say I'm Dose Buster because our job is to bust the dose as low as we can go.

We are grateful to have this opportunity to interface with the FDA and with other members of the community who are interested in the same goals as we are. We feel that it's important for the CDRH to maintain a core group of health physicists. We feel that the CDRH ought to be involved in or concerned about the supply of qualified radiation safety professionals to support the use of radiation devices.

HBS efforts in Congress and federal agencies over the past six years have been concentrated on raising awareness of the human capital crisis in health physics. FDA once was a major player through a public health service fellowship program in supporting academic university programs for health physics. It's not clear whether the PHS currently recognizes health physics as a discipline for officers in the public health service.

A few years ago, the PHS might have dropped it as a recognized allied health discipline due to lack of accreditation of academic programs. At the NIH when I started back in 1986, our staff of 25 health physicists, 13 were commission core officers. Today there are zero. We have no more commission core health physicists at the NIH.

We recognize and appreciate the CDRH stated intent to focus on the product use such as multi-slice CT scanners as opposed to just product development. We agree that the current concern has shifted from quality of product development to the varied product use.

In terms of partnership, in terms of the education arena, the HPS feels that we could best dovetail our efforts in this department. Most of the health physicists are out in the field and we interact with all segments of society being the schools, the teachers, the public, the patients, the physicians, the researchers, all segments, all aspects. And we've established ourselves as educators in the field of radiation safety.

One of our most popular features and services on our HPS website is "Ask the Expert" where members of the general public, students, patients will send questions in about how many x-rays can I have before I glow in the dark and if I stand by the microwave when I'm nuking a sandwich, how bad is that and what if I'm at elbow length. So they could be from very innocent to very serious questions to I've been diagnosed with this type of cancer. My physician recommends I get A, B and C. What do you think?

So we have a canned array of professional in health physics who diligently answer these questions and research and farm them out to other allied health care professionals if we're not equipped to answer those. We think that we should be able to bridge that resource and that knowledge and a lot of people know that that venue exists today that we would bridge that with the FDA, CDRH and their terms of public outreach and getting information out there to the community. Thank you very much.

FACILITATOR LESLIE: Thank you. That exhausts the list I have written down up here. I

guess the question now is are there others of you who would like to make a comment. Going once. Twice. Okay. We'll call the public comment period closed. All right.

Before this, I said I wanted to raise the question of collaboration and it goes all the way back to the first piece this morning. Somebody said what do you mean by and I think it was monitoring. But in this case, as this plan looks forward, maybe it's a decade long plan, I don't know, but as this plan looks forward and says here's some things that need to be done in the future and you don't ever see a government agency or actually any agency these days that does not talk about partnering, that doesn't talk about collaborating with a variety of stakeholders.

Here's no exceptions. For you in your various roles in your various organizations, my question, and I would love to have people get up here to the microphone and have your opinion about that, what is collaboration? Where should the bar be set? What constitutes satisfactory collaboration?

It's not sufficient in my view to simply

say CDRH, you provide the money and I'll show up and that's collaboration. So you all have a stake in this in some form or another and I guess when you think of your interaction with CDRH on the one hand, others of you in the room on the other, what should we strive for in terms of collaboration that acknowledges accountability where it belongs because somebody spoke to accountability? Was it you, Ellen? Somebody spoke to that and I'm not suggesting that accountability get move around and misplaced.

But I think there is a working together that comes with the concept of collaboration and I would very much like to have those of you in the room have a quite vocal say about that. I'd like to hear what you think about that. Fair question? Because we're going to get into it tomorrow to say what are the opportunities for collaboration. This whole plan is built on the notion that nobody can do it all by themselves. We actually have to help each other to get it done.

So my question is what in your view is satisfactory collaboration. What should we strive for

in that regard? Please come. We need for the transcriber to get this. So have at it.

MR. BALTER: Steve Balter again. I'm going to say this personally rather than response to an organization. I think the first part of collaboration as we saw in several of the talks is communicate, communicate, communicate. If we all know what each other is doing, a lot of the rest will work out. Budgets, authority are less flexible. We have to know rather than worrying with some of the things. A good collaboration, call them up and ask what they think.

FACILITATOR LESLIE: Good. Thank you. Others? Ellen, come. While Ellen is walking up here, one of those points I would say is a question for the subject and I think it may even have been you that says that I have a workforce that's aging. They're going to retire. Do I just look at you and say good to you or is there something else? Please.

MS. HAARS: Ellen Haars from State of Washington. Let me give you an example of what I call collaboration and let's use training. FDA has this

basic radiological health training and I think the state has a role. They should pay for the per diem and travel expenses of the student, probably pay some tuition but then FDA would get the instructor, get the setting. So it's two-sided. We're equal partners. It doesn't come down from Washington D.C. this is the way it is. They work together.

FACILITATOR LESLIE: Good. Thank you. Others? Please.

MR. BRITAIN: Bob Britain with NEMA. Collaboration is sort of an interesting issue when you have the regulator and the regulatee. Obviously manufacturers would like to collaborate on issues with the government and medical associations if the result of that collaboration will or might impact the design of the equipment, standards associated with the equipment and this is not an easy issue because of the arms length situation between regulators and industry but it's something that has to be worked through.

I'll give you a good example and that is in many cases we work very closely with the American College of Radiology. But with their accreditation

program, it was a real arms length situation and we were set aside as far as being invited in to help them with their accreditation program which could impact equipment and the way it's measured. So that's a good example.

We worked through a couple of situations with MRI where we were able to get in after the fact and do some improvements. Anyway, I just wanted to throw that on the table that collaboration isn't always easy although we really want it.

FACILITATOR LESLIE: Cool. Thank you. William.

MR. BENNER: You know one of the ideas when I hear the word collaboration within our industry what it means to me is that we would participate in helping CDRH accomplish their goals. Like for example if CDRH said we would trade this for some increase in training, training is something that we do on a regular basis. It's something we're set up to do. We could do very easily putting together a training program, things like that.

One of the things I'm thinking about is as

I heard problems with the CT machines and dosage and dosage measurement and there was a word that I don't really understand but it conjured up in my mind this dummy human that you throw into the machine and you kind of somehow get some kind of measurements off of this thing.

One of the things that's going through my mind as I hear each one of you and as I hear the CDRH reaching out for collaboration is that industry itself, the Siemens, the GEs, the people who are making these machines could participate in helping CDRH to accomplish their goals and also helping people who have reduced staffs. One of the things, I'm not sure if I'm the only one thinking along these lines, but as these staffers which are going to be retiring soon and you're wondering where you're going to come up with these new staffers, that's going through my mind is are there alternative ways of accomplishing the same things such as coming up with another way of testing, some sort of a more advanced dummy human that you throw into the machine.

Think about this. This may sound wacky

but this is possible. My company accomplishes impossible things all the time. Think about this. This FedEx box comes. It's this dummy human. You throw in the x-ray machine. It gets x-rayed. Then you FedEx it back. Then somebody analyzes the data that was experienced by the dummy human to figure out is it too high or too low. This is really possible. It may sound stupid or wacky or whatever but really this is the kind of really base level, easy to accomplish stuff that could be happening and the industry itself could be helping out with.

I bet if you asked Siemens what's the best way to test your x-ray machine. In addition to coming up with the machine, come up with the tester too. Yes, they can and they'll more than happy to help you guys do that. So I think that's the answer is industry participation. Sometimes it's really just figuring out what the question is and you never come up with the good idea until you ask the question.

A while back, HP had a saying which I love which they've dropped and we've adopted. It said "We never stop asking what if." So I think we all need to

start asking "what if." What if there was a FedEx dummy thing? It could happen.

FACILITATOR LESLIE: Good. Thank you. John.

MR. VILLFORTH: Sure glad I'm retired. I don't think I could deal with all this. I just want to again compliment the folks in the back of the room from CDRH (1) for being here. Could I ask for a show of hands of those of you who are from FDA other than ORA or CDRH? The senior people in FDA. Who's the most senior person in CDRH here? Is the Center director here? Deputy director? Does that tell you something?

Okay. This is such a big issue and I think the Center must be complimented for taking the time and putting this together and making this step in the right direction.

I think this is where collaboration starts. It starts with the fact that the juices flow as you hear all of these different organizations, all of you, and I thought it was very exciting to hear the attempts to say hey we want to work together and

that's wonderful. But we're down here to do two things, this and leadership. This is going to be hard to come by. I'll let the other speak for itself.

I don't have an answer other than going back to the basic Radiation Control for Health and Safety Act. There's a lot in here if you ever go back and read it. It's great reading. I think it's one of the -- Seriously, for those of you in the medical device area and with Bob Britain aborting and going over to medical device program in the early days, we used to talk about the fact that the Medical Device Regulation which was initiated by Congressman Paul Rogers as was this Radiation Control for Health and Safety Act, this is `68 and one is `76, the Device Act, the Device Act starts out by saying that all medical devices will be divided into three parts: Class 1, Class 2 and Class 3. If you fall in one of those three classes, here's the sequence of events that you must do.

The Radiation Control for Health and Safety Act I think is one of the most beautiful pieces of legislation because it says our job is to protect

the public from unnecessary radiation exposure and there's a whole bunch of tools in here that suggest how that might be done. As I said earlier, the main tool is performance standards. That's the basis of which it was said. But there are other important tools like I said, the defect, the recall provisions and so forth.

But there's a big section here about what could be called collaboration and working with other federal agencies, consult and maintain liaison with the Secretary of Commerce and the Secretary of Defense and Secretary of Labor, AEC and blah, blah and working together. There's also a comment in here about professional organizations and other scientific organizations which is another word I guess of saying collaboration. So there's good stuff in here. A lot of it's discretionary and a lot of it because of this and because of that have gotten lost. So I hope we can reinstate it. I hope what we're seeing here today with the leadership of John and the folks in the back of the room that you're going to start in the proper direction.

I played around with some numbers here. You were talking about training and education just to let you see how things have gone down the tubes. I wanted to share that with you. In the Heddie (PH) days starting after 1961, this is really ancient history, the training grants to institutions that came out of what was then the Bureau of Radiological Health, and I had nothing to do with this, amounted to about 30 to 35 training grants to academic institutions at the graduate level and about seven at the undergraduate level and many of you and many of the people you work with are probably the fruits of some of those programs that were funded.

Those abruptly ended in 1975 when they went back to zero. So there is no money coming out of this department, Health and Human Services, through CDRH to support any kind of graduate training program or technician training program. In addition to that, of course, there were research grants which went into universities which helped in a way to support research assistantships for various projects related. So that helped amplify things.

With regard to the short-term training programs, I don't have the actual numbers but I remember the statistics. Back in 1969 when I first had the opportunity to be the Director of the Bureau of Radiological Health that year we conducted 99 class weeks of training in all of the facilities. Training was done at Rockville. It was done at Montgomery, Alabama, Las Vegas and Winchester, Massachusetts. Not all of that was the type of radiation we're talking about here. A lot had to do with environmental radiation. But 99 weeks. Classes were going on continuously in those programs.

Those I guess are down except for what's being done in MQSA essentially zero. I don't know whether EPA is doing any thing in this. They're not. Okay. But that's the problem you have to face where again we're talking about money, recognition and so forth because I think the concern of the Health Physics Society is real and very clear. I don't know the solution to it. I just know that this kind of a discussion, the fact that there will be a written record and an opportunity for everybody to make their

points known is going to be a real step in the right direction and I appreciate what leadership you've expressed here.

FACILITATOR LESLIE: Great. Thank you, John. One word in here in between. I would offer to you. John said something really important in the sense that the leadership piece here is a critical one and I'm reminded.

To illustrate let me do this. Last week I was actually doing a similar sort of activity for the President's Cancer Panel and at one point in that meeting, one of the panel participants asked Dr. Margaret Kripke from M.D. Anderson who was one of the panel members, we were discussing this recommendation that said the NCI was supposed to create this task force and this panel member said to Dr. Kripke who is this task force. And she looked around the panel who like you was a selected group of people who cared very much about the subject and she said, "It is you."

That is true in this room. You all are the ones who care. You are the ones who saw fit to come and be here and be part of this. I think you

with John and his staff share the leadership responsibility, John, that you so correctly point to to make this move forward because I think it is you all that will do that. So please.

DR. READ: Thank you. Dr. Sandra Read for the American Academy of Dermatology. The FDA and the AAD have participated and cooperated in the past in scientific consensus conference on issues of mutual interest such as skin cancer, Vitamin D levels, tanning salon and regulation and we are very grateful for that association in the past. I think that is the best form of collaboration is to continue to share our experts and our scientific knowledge and we look forward to a future working with this committee. Thank you.

FACILITATOR LESLIE: Cool. Thank you. Anybody else? Please. The point you keep making is you have to get in the room and talk to each other. If you don't do that, not much else happens. You're on.

MR. CYRE: Jim Cyre from Phillips Lighting Company. I've been listening and at the risk of going

back to something elementary I keep hearing something that harkens maybe to Quality 101 which many times gets screwed up in the implementation as well. But really what constitutes collaboration is (1) total trust by the community of stakeholders. The willingness to listen and accept breaking or shifting of paradigms, the interesting example of the FedEx box, I don't know but is there other ways of doing it?

I've heard a lot today about consensus standards. Anybody here ever been involved in the development of a so-called consensus standard that they didn't feel good about. Well, the same deal here. I have two. But it comes back to it's not taking a vote and the majority wins. It's finding solutions that meet the requirements of all of the stakeholders and that really I think is the challenge here today.

FACILITATOR LESLIE: Cool. Thank you. Anybody else want a crack?

MR. McCORMICK: Luke McCormick with Customs and Border Protection again and I have a little bit different view on this because I'm not

really regulated by you guys. I'm an enduser and I think maybe a little of the collaboration the way we can get into it is the way I collaborate with our manufacturers.

I don't know. I'm sure some of the manufacturers out there saw the paper today and realize that we have a couple hundred million dollars budgeted for non intrusive inspection equipment this year. I have a lot of our manufacturers who will very willingly fly out to see us and take our suggestions for the radiation safety that we want input into the systems that we're going to buy. It's that bottom line that somehow makes people collaborate much more effectively.

FACILITATOR LESLIE: Doesn't it though?

MR. McCORMICK: I think maybe that's one thing we can do is look at the end users, the medical community, the laser users. Get them involved in the collaboration because I have certain needs in my non intrusive imaging. I would hate to have your regulations only reflect my needs. DoD has the need for this type of imaging as well and they have some

needs that I don't think I need. So your regulation is going to have to be from a bunch of different users of the same type of equipment and unfortunately in NII there aren't a lot of us that use this.

FACILITATOR LESLIE: Great. Thank you. anybody else? You know it's that old business of finding the solution that you can all support even though it might not be your first choice. But it gets to the point of if we can find a way where we can move it forward without winding up it's either my way or your way and we'll let the lawyers work it out. Okay. Any other comments? John, do you want to say anything about the topic I raised here before I talk about tomorrow? Apparently yes.

DEPUTY DIRECTOR McCROHAN: When invited, I almost always speak. I wanted to in particular thank John for his comments and the woman from NIH representing the Health Physics Society. There you are. Okay. I can't keep track of time anymore. I'm getting too old for that. But it was two, three years ago that I finished my 30 years career in the Public Health Service as a commissioned officer and I came to

the Public Health Service in part through the PHS training fellowships which incidentally funded by graduate career at the University of Washington in Seattle. So lot of little connections here.

I also wanted to react to a comment that was made about, I think it was by Bob Britain, the situation in which we sometimes find ourselves where we're held at arm's length from certain developments and just reflect on the fact that back before the advent of MQSA, back at the time when notwithstanding I was part of FDA, a regulatory agency, I didn't know how to spell that word and when I was more in an educational mode and where collaboration was what you did every day, there were a number of organizations with whom I had what I at least considered to be a very productive relationship. CRCPD was certainly one. ACR was another.

Then MQSA passed and then ACR applied to the accrediting body and then they were being regulated by us in that respect. I think it's fair to say that that had for me a somewhat sort of chilling effect and I think that's too bad. I don't know that

there was a way to avoid that. But I think Bob has a good point in terms of particularly the manufacturers in collaboration with the regulatory agency and so on. I think that is difficult.

On the other hand, I think FDA in this context is worth looking at if I can put it this way in a somewhat schizophrenic fashion. We are certainly a regulatory agency. We have that relationship with a number of our stakeholders. But there's a sense in which we're another kind of an agency. We're a public health agency and the public health is I think what we're primarily about. That's why we engage in regulation but it's also why we do other things.

And I think to the extent that there are opportunities to collaborate on things which are not of a regulatory nature, we shouldn't let our nature as a regulatory agency get in the way of that. I say that in particular because to the extent that we see the public health problems that we are faced with as being problems of use with the sole exception of mammography, we don't have a regulatory role. We don't have the authority, the responsibility, to

regulate the endusers and yet I think we have the public health responsibility to try to do what we can to provide those endusers with the appropriate information, to what we can to educate, to motivate, to challenge those people to do the best job that they can and I think that's a mission that we share with lots of you folks and I wouldn't want to see our regulatory role get in the way of the potential for collaboration in those areas.

For our friends in the states who do have the authority to regulate use, I would say what I've said more than once over our 30 year association and that is there are certain programs that we have that are nonregulatory like NEXT for example which is the basis for reference levels or expected values of exposure for certain examinations that we think ought to be applied in a nonregulatory fashion.

I think at the same time there are things which can be done by states as regulators of the endusers particularly for example in medical facilities such as requiring medical facilities using x-ray systems to have a quality assurance/quality

control program to maintain some form of oversight, to have a medical physicist alla MQSA come in on an annual basis and do an assessment of not just the machine but how the facility is maintaining not just the machine but it's whole quality control program and assuring that the exposures to their patients are reasonable. And I think sort of oversight would be very helpful but I think again there's this issue of balance and how do we do that without creating a barrier that may not need to exist amongst those of us who would otherwise be able to collaborate given the regulatory nature as Bob was saying of some of our responsibilities.

I think in the training arena we'll talk about this certainly tomorrow there's a real opportunity I think here to have some effective collaboration. The days unfortunately, John, are long past when HHS or whoever we were at the time can mount 99 weeks worth of training in a year much less support the institutions of higher education where I got my advanced degree. Thank you very much.

But I think that there are in the audience

any number of people who have access to information which would be useful in a training environment, have actual training programs and courses and so on and so forth. I think what's called for is bringing that to bear on the training if you want to think of it in those terms of the public, of endusers and regulators because I think it's in the bottom-line vested interest of the regulated community to see to it that the regulators know what they're doing.

If you have a regulator come into your facility, into your manufacturing plant, who is not well versed in the topical area that they have to deal with, I think you'll find that they're going to do a lot more harm than good. So I think that it is in everyone's interest that we be as smart as we can be. I think that the states would agree and I'll leave it at that until tomorrow.

FACILITATOR LESLIE: Okay. Let me talk a little bit about tomorrow and then we'll get out of here. On your name tag, you will see a number. That number is to be the starting group you'll go to tomorrow once we launch out of there. The intention

of tomorrow is take the three new areas of intent in this CDRH plan of standards, monitoring and education, set up essentially round-robin groups and allow each of you the opportunity to go to each one of those for about an hour and have your say.

Now when we originally conceived this meeting, I must say we truthfully envisioned that probably 50 people would find this interesting. So we were envisioning the groups would be a little smaller than we're turning to be. So there will be a little bit of cooperating with each other tomorrow so that everybody gets to have their say.

But what we're really wanting you to do is in each of those areas with our folks in the room talk to the pieces that are these. What are the issues looking ahead that have to be solved with regard to standards, monitoring, education? What should be the priorities over the next couple of years? You know it's this limited money and energy thing. I only got X amount of folks. I only got X amount of money. And I can't do it all. What should we put real muscle behind knowing that that meant something else didn't

get quite as much? Your view of what those priorities ought to be will be very important and very interesting to hear.

Then the third piece is the thing that we've just been talking about. What are the opportunities to collaborate that you see? I'm hoping you actually see some rather specific things so that you can say "Hey, you and me. Let's get together and work up a piece of X and do this with it." I'm hoping some things come out of that like that. But bottom line, it's what are the things that have to get solved going forward to make this thing move, to head in the direction to benefit the public health, the thing that you'll in this room for. And then the priorities and then the opportunities to collaborate.

So what we're wanting to do tomorrow is cycle through giving you an opportunity to be in each of those groups and then come back in here, hear what the themes out of those groups were before you leave because those will be we have facilitators for each of those groups. We'll having somebody working a laptop to try to make some sense out of all that and out each

of those, I'm expecting you to see five, ten, fifteen item list that says these are the things said most often. These are the themes that came out of the days' discussions on standards, on monitoring, on education. It may surprise all of us what comes back out of that because you'll see it as you go around.

There is a piece on the schedule tomorrow afternoon that's 3:15 p.m. which I think John and I'll be up here in front of room and it's called open discussion and it's for this. We're asking you to spend most of the day focusing on those three areas. There may be some other things you think we ought to be talking about. There may be some other things you think are important and that will be the opportunity to get that on the table because if it's not be said and it needs to be said, we want to hear it because it will then provide the basis, all of this provide the basis, so how do we move this thing forward.

Deals will get make later. Plans will get made and talked about later and work structured because what's that old line about ultimately it all evolves into hard work. All of this conversation is

terrific but sooner or later somebody had better do something or it's just been a nice talk. We have to get to that but that's a little down the road.

What I'm envisioning is we'll come in here tomorrow morning. We'll bang the gavel at 8:30 a.m. I think the coffee is ready at 7:45 a.m. earlier. Coffee and the continental breakfast will be there as this morning. We'll get going and I'll get you launched out of here into these groups fairly quickly and we'll spend the day doing that. I think you'll find tomorrow different than today and I'll hope you'll find it a very good day.

Anything before we draw it to a close and hopefully adjourn in here and have a glass of iced tea, a cup of coffee or something else? Anything? Cool. See you in the morning and if you can have a drink of something, please do. Thank you for a good day.

(Whereupon, at 4:13 p.m., the above-entitled matter concluded.)